

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CARL D. CACHIA, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

BELLUS HEALTH INC., ROBERTO
BELLINI and FRANCOIS DESJARDIS,

Defendants.

Civil Action No.: 1:21-cv-02278-GBD

CLASS ACTION

DEMAND FOR JURY TRIAL

**AMENDED CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

TABLE OF CONTENTS

I.	NATURE OF THE ACTION	1
II.	JURISDICTION AND VENUE	6
III.	PARTIES	7
	A. Plaintiff	7
	B. Defendants	8
	1. BELLUS	8
	2. The Individual Defendants.....	8
	3. Defendant Smith	10
	4. The Underwriter Defendants.....	12
IV.	CLAIMS ASSERTED IN THIS COMPLAINT.....	16
V.	SUBSTANTIVE ALLEGATIONS	18
	A. Relevant Background.....	18
	1. The Treatment for Refractory Chronic Cough: An Unmet Need with a Multi-Billion Dollar Addressable Market.....	18
	2. The FDA Requires Submission of a New Drug Application Demonstrating Substantial Evidence that a Treatment is Effective	20
	3. BELLUS's Successful Phase 1 Trial for BLU-5937	22
	4. BELLUS's Competitors Successfully Complete Their Phase 2 Trials Before BELLUS Even Begins Enrolling Patients in its Phase 2 Trial	23
	B. Defendants' Touting of Competitors' Clinical Trials Concealed Design Flaws in BELLUS's Phase 2 Trial and Allowed BELLUS to Successfully Raise Capital	30
	1. Defendants Generated Investor Interest in the IPO by Capitalizing on Competitors' Clinical Studies and Strengthening its Management Team	30
	2. BELLUS Successfully Completes its IPO.....	32
	3. Throughout the Class Period, Defendants Continued to Mislead Investors about BELLUS's Phase 2 Trial by Likening it to Competitors' Trials	34

4. As BELLUS's Competitors Released More Data Throughout the Class Period, the Market Reacted Positively in Anticipation of RELIEF Results	36
5. Despite the Increasingly Public Data, BELLUS Failed to Adjust its Phase 2 Design or Disclose the Growing Risk of Failure as a Result of the Low Number of Severe Cough Enrollees	40
VI. THE 1934 ACT CLAIMS.....	44
A. Defendants' Materially False and Misleading Statements and Omissions During the Class Period.....	45
B. Additional Scienter Allegations	64
1. BELLUS, the Individual Defendants, and Defendant Smith.....	64
2. The Underwriter Defendants.....	68
C. Loss Causation	70
VII. THE 1933 ACT CLAIMS.....	76
VIII. PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)	81
IX. NO SAFE HARBOR	83
X. CLASS ALLEGATIONS	83
XI. CLAIMS FOR RELIEF	85
XII. PRAYER FOR RELIEF	97
XIII. JURY TRIAL DEMAND	97

Lead Plaintiff Carl D. Cachia (“Plaintiff” or “Mr. Cachia”), by and through his attorneys, individually and on behalf of all others similarly situated, asserts the following allegations against BELLUS Health Inc. (“BELLUS” or the “Company”), Roberto Bellini (“Bellini”), François Desjardins (“Desjardins”), Dr. Catherine Bonuccelli (“Bonuccelli”), Dr. Jacky Smith (“Smith”), Jefferies LLC (“Jefferies”), Cowen and Company, LLC (“Cowen”), Guggenheim Securities, LLC (“Guggenheim Securities”), Robert W. Baird & Co. Incorporated (“Baird”) and Bloom Burton Securities Inc. (“Bloom”) (collectively, “Defendants”), based upon personal knowledge as to his own acts and on information and belief as to all other matters.¹ Plaintiff based this information and belief on, among other things, the investigation conducted by his counsel, which includes a review of: U.S. Securities and Exchange Commission (“SEC”) filings by BELLUS; securities analysts’ reports and advisories; the Company’s press releases and other public statements; media reports; and other publicly available information. Counsel’s investigation into the matters alleged herein is ongoing and many relevant facts are known only to Defendants or are exclusively within their custody or control. Plaintiff’s investigation indicates substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of Plaintiff and on behalf of a Class consisting of all persons or entities who purchased or otherwise acquired (a) BELLUS common stock pursuant or traceable to the Registration Statement and Prospectus issued in connection with the Company’s September 2019 initial public offering (“IPO”) of its common shares (collectively, the “IPO Documents”) and/or (b) BELLUS securities between September 5, 2019 and July 6, 2020, both dates inclusive (the “Class Period”). This Action alleges fraud-based

¹ Unless otherwise noted, internal citations are omitted and emphasis is added throughout.

claims under the Securities Exchange Act of 1934 (the “1934 Act”) and, entirely separately, strict liability-based claims under the Securities Act of 1933 (the “1933 Act”).

2. BELLUS is a clinical-stage biopharmaceutical company whose lead development is BLU-5937, a highly selective P2X3 antagonist for the treatment of chronic cough. When speaking to investors throughout the Class Period, BELLUS misrepresented and omitted material information about the clinical study of BLU-5937.

3. Chronic cough—generally defined as a cough lasting at least eight weeks—poses an untapped, multi-billion-dollar treatment market. Traditional pharmacologic treatments such as nonprescription products and opiates have proven to ineffective and pose significant safety risks, thus, pharmaceutical developers began seeking new experimental chronic cough agents, including those that target specific receptors or channels in the peripheral sensory neurons, to try and create a superior alternative and capture the market. Specifically, clinical studies have shown that the P2X3 receptors play an important role in the activation of sensory neurons integral to the cough reflex, making that receptor a promising therapeutic target in neuropathic conditions, such as chronic cough. Although roughly 10% of the adult population in most developed countries suffers from chronic cough, and about 50% of cases cannot be explained by an underlying cause (*i.e.* Refractory Chronic Cough (“RCC”)), the U.S. Food and Drug Administration (“FDA”) has not yet approved a P2X3 antagonist as an alternative therapeutic treatment. The potential financial payoff, therefore, has drawn big pharmaceutical companies like Merck & Co. (“Merck”) and Bayer AG (“Bayer”) into the race to develop the first FDA-approved P2X3 antagonist.

4. From the start, Merck was well ahead of the pack, setting the pace and creating a roadmap for competitors. By March 2018, Merck had completed successful Phase 2 clinical trials demonstrating that its P2X3 antagonist, gefapixant, was effective in patients with chronic cough

at a high cough frequency (*e.g.*, with a mean awake cough frequency of 56.9 coughs per hour (c/h) in its first Phase 2b trial and 40.3 c/h in its second Phase 2b trial). While Merck was poised and ready to begin its Phase 3 clinical trials, gefapixant had problems; its users experienced significant adverse effects (AEs) including taste alteration or taste loss.

5. Accordingly, BELLUS saw a perfect opportunity—follow Merck’s roadmap to establishing efficacy, while creating a more tolerable treatment. BELLUS developed BLU-5937 to target the same primary receptor (P2X3) targeted by gefapixant, while avoiding an additional receptor (P2X2/3) that is associated taste, causing gefapixant’s taste-related AEs. According to BELLUS, its executives and advisors, BLU-5937’s efficacy was virtually a foregone conclusion based on its high selectivity. Indeed, throughout the development process of BLU-5937, BELLUS utilized Merk’s clinical success with gefapixant, as an indication that it be able to prove the efficacy of BLU-5937 in its own clinical trial.

6. By November 2018, BELLUS had completed its Phase 1 clinical study of BLU-5937. Although it was behind Merck in the clinical development process, BELLUS touted positive preclinical and Phase 1 study results demonstrating that BLU-5937 was more “selective” than gefapixant—showing a significant reduction in cough, with no taste loss side effect. In April 2019, the FDA accepted BELLUS’s Investigational New Drug (“IND”) application, clearing the way for a Phase 2 clinical study (“RELIEF”) to assess the efficacy, safety, and tolerability of BLU-5937 at four doses (25, 50, 100 and 200 mg) in patients with chronic cough. In July 2019, the Company began enrolling patients in the RELIEF trial.

7. But BELLUS needed money. On September 3, 2019, while in the middle of the RELIEF study, BELLUS announced its intent to raise \$60 million in a U.S. IPO. By that time, two other companies, Bayer and Shionogi, had successfully completed Phase 2 clinical studies showing

that treatments targeting the P2X3 receptor were effective in patients with severe chronic cough. Defendants touted that the data presented by these competitors, as well as Merck's progress, were encouraging for BELLUS's ongoing study and validation of BLU-5937. Indeed, all four companies had developed P2X3 antagonist, however the degree of selectivity is what BELLUS claimed would set BLU-5937 apart from the rest, eliminating taste-related AEs. Further, Defendants conveyed that the RELIEF study followed the same design and parameters as Merck's successful studies, thus demonstrating efficacy was of no concern. Bolstered by Defendants' representations, the IPO was well-received by the market, and BELLUS raised \$70 million (\$10 million more than initially planned).

8. Unbeknownst to investors, however, BELLUS's Phase 2 study materially differed from Merck's and faced enormous undisclosed risks of failure. Merck's Phase 2 studies had demonstrated that, there was a direct correlation between cough frequency (*i.e.*, patients who had a cough frequency of 56.9/40.3 c/h) and the efficacy of P2X3 inhibitors. This distinction is critical. A lower frequency cough, although chronic, is much more likely to arise from alternative sources uncorrelated with the P2X3 receptor. As such, the data did not support efficacy in patients with lower cough frequency (*e.g.*, 10 or less times per hour). Therefore, it was vital for the RELIEF study to include a patient population with a high average number of coughs per hour—*i.e.*, patients whose conditions actually correlated with the P2X3 receptor targeted by BELLUS's BLU-5937.

9. During the IPO and throughout the Class Period, however, BELLUS was struggling to enroll patients with a higher cough frequency. In Merck's earlier studies, the enrolled patients' median awake cough frequency had been 28.9 coughs per hour. In RELIEF, the patients enrolled had a mean awake cough frequency of around 25 c/h. Defendants had actual knowledge of, or access to, the difficulties enrolling the target population of patients. But in the IPO Documents and

throughout the Class Period, Defendants failed to disclose those facts.

10. Instead, Defendants made repeated misrepresentations and omissions that artificially inflated the price of BELLUS's securities. Defendants conveyed that the RELIEF study mirrored the successful clinical studies by Merck (as well as by Shionogi and Bayer) but posed the added benefit of eliminating the AEs of taste alteration or taste loss. Under those circumstances, as described by Defendants, the trial posed a low risk of failure. At worst, BLU-5937 would be nominally less effective at treating chronic cough or posed similar AEs as the competing treatments. At best, BLU-5937 would be as effective, if not more, while eliminating those AEs. But Defendants had failed to enroll the target patients and, instead, had enrolled patients with low frequency chronic cough.

11. During and after the IPO, Defendants misrepresented those facts and provided misleading information about the RELIEF study's progress and success. Then, during an April 7, 2020 investor call, Defendants partially revealed the truth, announcing the possibility of a Phase 2b trial if the ongoing Phase 2 trial failed to indicate a minimum efficacy dose. On this news—portending poor efficacy results—the Company's stock price fell \$1.00, or 9%, to close at \$10.00 after two days of heavy trading.

12. On July 6, 2020, Defendants finally revealed the truth. The majority of enrolled patients in the RELIEF study had low cough counts and, consequently, BLU-5937 had failed to meet its primary endpoint and was not considered significantly better than a placebo at reducing the frequency of those patients' coughs. In effect, BELLUS had spent years and millions of dollars to test BLU-5937 on the wrong patients. Worse yet, BLU-5937 could have exceeded expectations if Defendants had enrolled patients with a high cough frequency (as done in the competitors' successful studies). Specifically, the RELIEF study showed a "clinically meaningful and highly

statistically significant” effect on a subset of patients who had high cough counts (with a cough frequency of 32 c/h)—*i.e.*, the patient population BELLUS should have used to set its primary endpoint. Accordingly, the Company was planning a Phase 2b trial focused on those patients.

13. This news was detrimental for investors. BELLUS’s sole drug candidate had failed its Phase 2 trial. Defendants had repeatedly emphasized that BELLUS was following the study protocols utilized by Merck and insinuated that based on the high selectivity of BLU-5937, the RELIEF study would prove BLU-5937 to be the superior P2X3 antagonist in comparison to Merck’s, Bayer’s, and Shionogi’s, based on the data from the competitors’ Phase 2 trials, yet the RELIEF study failed precisely because Defendants fundamentally deviated from those protocols. Consequently, BELLUS had fallen further behind Merck and the other competitors and had to undertake the cost, delay, and risks of a second Phase 2 trial. In response to those disclosures, the Company’s stock price plummeted over 75% over two days of heavy trading volume.

14. As a result of Defendants’ materially false and misleading statements and/or omissions that obscured the true facts in the IPO and throughout the Class Period until they were partially revealed on April 7, 2020 and fully revealed on July 6, 2020, causing precipitous declines in the market value of BELLUS’s securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

15. Counts One and Two arise under Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

16. Counts Three, Four and Five arise under Sections 11, 12(a)(2) and 15 of the 1933 Act, 15 U.S.C. §§ 77k(a), 77o(a).

17. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. § 1331, Section 22 of the 1933 Act, 15 U.S.C. § 77v, and Section 27 of the 1934 Act, 15 U.S.C. § 78aa, because this is a civil action arising under the laws of the United States.

18. Venue is proper in this District pursuant to Section 22 of the 1933 Act, 15 U.S.C. § 77v, Section 27 of the Exchange Act, 15 U.S.C. § 78aa(c), and 28 U.S.C. § 1391(b)-(d). Specifically, substantial events giving rise to the claims alleged herein occurred in this District, including: (i) many of the false and misleading statements were made in or issued from this District; (ii) many of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, were made or issued from this District; and (iii) the Company effectuated the registration and delivery of BELLUS securities on the NASDAQ Global Select Market (“NASDAQ”), which is located in this District.

19. In connection with the acts, transactions, and conduct alleged herein, Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including, without limitation, the U.S. mail, interstate telephone and other electronic communications, and the facilities of the NASDAQ, a national securities exchange.

III. PARTIES

A. Plaintiff

20. Plaintiff Cachia purchased or acquired BELLUS securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the disclosures and/or materialization of Defendants’ conduct alleged herein. In addition, Plaintiff Cachia purchased BELLUS common stock traceable to the Company’s false and/or misleading IPO Documents and was damaged thereby.

B. Defendants

1. BELLUS

21. Defendant BELLUS is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders.

22. The Canadian Company was incorporated on April 12, 2012, under the Canada Business Corporations Act, as successor of BELLUS Health Inc., a company incorporated on June 17, 1993 (formerly known as Neurochem Inc. prior to April 15, 2008). The Company has two wholly owned subsidiaries, BELLUS Health Cough Inc., which is also incorporated under the Canada Business Corporations Act, and BELLUS Health Corp. incorporated under the laws of the state of Delaware.

23. The Company maintains its headquarters in Laval, Québec and its common stock is listed and trades on the NASDAQ under the ticker symbol “BLU.”

2. The Individual Defendants

24. Defendant Bellini is, and has been since January 1, 2010, serving as the President and Chief Executive Officer (“CEO”) of BELLUS. Prior to his appointment as CEO, Mr. Bellini oversaw the licensing and partnering activities of BELLUS as its Vice President, Business Development. At that time, he had had 8 years of experience with the Company’s products, science, and the industry in which it operated. Mr. Bellini graduated from McGill University in Biochemistry.

25. Defendant Desjardins is, and has been since 2009, serving as the Senior Vice President (“SVP”), Finance of BELLUS. He is responsible for the Company’s finance and administration and has been with the Company since joining in 2003 as Director, Finance and Control. Mr. Desjardins has over 20 years of experience in the biopharmaceutical industry, having held the position of Corporate Controller at BioChem Pharma for six years. He is a member of the

Ordre des comptables professionnels grees du Québec (OCPAQ) and graduated from Sherbrooke University in Commerce.

26. Defendant Bonuccelli, MB, is, and has been since August 26, 2019, serving as the Chief Medical Officer (“CMO”) of BELLUS. Prior to joining BELLUS, Dr. Bonuccelli held various leadership positions focusing on the late-stage clinical development of large and small molecule programs in the respiratory and inflammation therapeutic areas. During her more than 20-year tenure with AstraZeneca, she served in many roles, including Global Medicines Clinical Vice President for the Inflammation, Neuroscience, & Respiratory Therapeutic Area, and Therapy Area Clinical Vice President, Respiratory and Inflammation. In these positions, she had oversight for all aspects of late-stage clinical development, including product strategy and creation of Phase III-IV study protocols and design for inhaled, oral, and biologic products including Symbicort and Fasenra. She was also responsible for designing and delivering brand lifecycle management opportunities, creating long-term portfolio strategies, and managing medical and scientific staff. Dr. Bonuccelli subsequently spent more than four years serving as US Medical Affairs Respiratory Therapeutic Area Head for GSK. In this capacity, she oversaw all medical support activities for the company’s portfolio of respiratory treatments. Dr. Bonuccelli earned her Bachelor of Medicine, Bachelor of Surgery (“MB”), and was an Intern, Resident, Research Fellow, and Clinical Fellow, at Johns Hopkins University in Baltimore, Maryland. She has authored 31 publications and abstracts, is a member of several prominent boards, and has been licensed in three states.

27. Defendants Bellini, Desjardins, and Bonuccelli are collectively, referred to hereinafter, as the “Individual Defendants.”

28. Each Individual Defendant was directly involved in the management and day-to-day operations of BELLUS at the highest levels and was privy to confidential proprietary

information concerning BELLUS and its business, operations, drug products, drug product development, competition, and present and future business prospects *via* internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or Board of Directors meetings and committees thereof, as alleged herein.

29. Because of their positions with the Company, the Individual Defendants were able to or did control the drafting, producing, reviewing and/or dissemination of the false and/or misleading statements and information alleged herein, were aware of, or recklessly disregarded, the false and/or misleading statements being issued regarding the Company, and/or approved or ratified these statements, in violation of the federal securities laws.

30. Further, as officers and controlling persons of a publicly held company whose common stock is registered with the SEC pursuant to the Exchange Act and trades on the NASDAQ, which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations, business, drug products, drug product development, competition, and present and future business prospects. In addition, the Individual Defendants each had a duty to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded common shares would be based upon truthful and accurate information.

31. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

3. Defendant Smith

32. Defendant Smith, MB, ChB, FRCP, PhD, is a Professor of Respiratory Medicine at

the University of Manchester, United Kingdom, and an Honorary Consultant at the University Hospital of South Manchester NHS Foundation. At all relevant times, Dr. Smith served as the Principal Investigator of BELLUS's Phase 2 RELIEF trial of BLU-5937 and/or the Chairman of the Clinical Advisory Board. While serving as an advisor for the Company, Dr. Smith ran a multi-disciplinary research team whose focus was on understanding mechanisms underlying pathological cough, and a regional clinical service seeing patients with refractory chronic cough. Her main research interests were focused on developing new endpoints in cough monitoring, understanding the mechanisms underlying cough in respiratory diseases and the testing of novel anti-tussive therapies.

33. In addition to her role as Principal Investigator and Chair of the Clinical Advisory Board, Defendant Smith led at least two Key Opinion Leader ("KOL") meetings hosted by the Company. On July 16, 2019, Dr. Smith led the discussions regarding the unmet medical need related to chronic cough and a review of current therapies in development, including P2X3 antagonist.² Then, on May 27, 2020, Dr. Smith, again, led a KOL meeting, hosted by BELLUS, to discuss the state of chronic cough treatment, including BLU-5937.³

34. Defendant Smith was directly involved in the management and day-to-day operations of the Company's primary focus, the clinical study of BLU-5937. As such, Defendant Smith was privy to confidential proprietary information concerning the Company and its business, operations, drug products, drug product development, competition, and present and future business prospects *via* internal corporate documents, conversations and connections with other corporate

² BELLUS Health, Inc., Management's Discussion & Analysis (Ex. 4.6) (Sept. 3, 2019) https://www.sec.gov/Archives/edgar/data/1259942/000114420419043097/tv528044_ex4-6.htm.

³ BELLUS Health, Inc., Management Discussion & Analysis (Ex. 99.2) (May 14, 2020) https://www.sec.gov/Archives/edgar/data/0001259942/000110465920061708/tm2019605d1_ex9-2.htm.

officers and employees, attendance at management and/or Board of Directors meetings and committees thereof, as alleged herein.

35. Because of her position with the Company, Defendant Smith was able to and/or did control the drafting, producing, reviewing and/or dissemination of the false and/or misleading statements and information alleged herein, was aware of, or recklessly disregarded, the false and/or misleading statements being issued regarding the Company, and/or approved or ratified these statements, in violation of the federal securities laws.

36. Further, as a controlling person of a publicly held company whose common stock is registered with the SEC pursuant to the Exchange Act and trades on the NASDAQ, which is governed by the provisions of the federal securities laws, Defendant Smith had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations, business, drug products, drug product development, competition, and present and future business prospects. In addition, Defendant Smith had a duty to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded common shares would be based upon truthful and accurate information.

37. Accordingly, Defendant Smith is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

4. The Underwriter Defendants

38. Defendant Jefferies operates as an investment banking firm, serving customers worldwide. Jefferies provides equity capital markets, debt capital markets, mergers and acquisitions, restructuring and recapitalization, and other strategic advisory services. Defendant Jefferies is incorporated under the laws of the State of Delaware and maintains its principal

executive offices at 520 Madison Avenue, New York, New York, 10022. Defendant Jefferies served as an underwriter and joint bookrunner for the Company's IPO.

39. Defendant Cowen is registered as a broker-dealer with the SEC and is a member in good standing with FINRA. Defendant Cowen is incorporated under the laws of the State of Delaware and is a wholly owned subsidiary of the publicly traded Cowen, Inc. Cowen, Inc. is a diversified financial services firm that, together with its consolidated subsidiaries, provides investment banking, research, sales and trading, prime brokerage, global clearing, securities financing, commission management services and investment management. Defendant Cowen maintains its principal executive offices at 599 Lexington Avenue, New York, New York, 10022. Defendant Cowen served as an underwriter and joint bookrunner for the Company's IPO.

40. Defendant Guggenheim Securities is the investment banking and capital markets business of Guggenheim Partners. Guggenheim Securities assists, in relevant part, with capital raises through public and private offerings of equity and equity-linked securities, debt, and structured products. Guggenheim Securities is incorporated under the laws of the State of Delaware and maintains its principal executive offices at 330 Madison Avenue, New York, New York, 10017. Defendant Guggenheim Securities served as an underwriter and joint bookrunner for the Company's IPO.

41. Defendant Baird is an American multinational independent investment bank and financial services company, providing in relevant part, advisory and financing services that help publicly traded companies, private companies, entrepreneur-owned businesses, and private equity firms around the world achieve their business objective such as equity capital market and capital advisory. Defendant Baird is incorporated under the laws of the State of Wisconsin and maintains

its principal executive office at 777 E Wisconsin Avenue, Legal Department, Milwaukee, WI 53202. Defendant Baird served as an underwriter and lead manager for the Company's IPO.

42. Defendant Bloom Burton Securities operates an investment banking firm, serving customers, in relevant part, with raising funding through a range of securities to suit the capital requirements, or risk and return objectives, of companies and investors, from equity and debt issues to private placements or participating in selling groups of public offerings. Defendant Bloom Burton Securities is a wholly owned subsidiary of Bloom Burton & Co., is incorporated under the laws of the State of Delaware and maintains its principal executive office at 65 Front Street East, Suite 300, Toronto, Ontario, M53 1B5. Defendant Bloom Burton Securities served as an underwriter and co-manager for the Company's IPO

43. Defendants Jefferies, Cowen, Guggenheim Securities, Baird, and Bloom Burton Securities are collectively, referred to hereinafter, as the "Underwriter Defendants."

44. Each Underwriter Defendant agreed to purchase BELLUS common stock (*see infra*) and was given the option to purchase up to an aggregate of 1,478,873 additional common shares from the Company. The Underwriter Defendants each served as a financial advisor for and assisted in the preparation and dissemination of the Company's materially false and/or misleading IPO Documents.

45. The chart below sets forth the number of common shares the Underwriter Defendants agreed to purchase in the IPO:

<u>Underwriters</u>	<u>Number of Common Shares</u>
Jefferies LLC	3,943,662
Cowen and Company, LLC	2,957,746
Guggenheim Securities, LLC	1,971,831
Robert W. Baird & Co. Incorporated	739,437
Bloom Burton Securities Inc.	246,479
Total	<u>9,859,155</u>

46. The Underwriter Defendants are primarily investment banks which specialize, *inter alia*, in underwriting public offerings of securities. As the underwriters of the IPO, the Underwriter Defendants earned lucrative underwriting fees for their participation.

47. In addition, the Underwriter Defendants met with potential investors and presented highly favorable but materially false and/or misleading information about the Company, its business, operations, drug products, drug product development, competition, and present and future business prospects, or omitted to disclose material information required to be disclosed under the federal securities laws and applicable regulations promulgated under those laws.

48. The Underwriter Defendants served as financial advisors, assisted BELLUS and the Individual Defendants in preparation and dissemination of the IPO Documents and had ultimate authority over the content of the IPO Documents, and the Underwriter Defendants' names were prominently displayed on the first page of the IPO Documents.

49. As a result, the Underwriter Defendants were negligent for stating that the IPO Documents were prepared accurately and in accordance with the rules and regulations governing their preparation. They also purported to conduct an adequate and reasonable investigation into the business, operations, products, assets and plans of the Company, an undertaking known as a "due diligence" investigation.

50. During their due diligence, the Underwriter Defendants had continual access to confidential corporate information concerning the Company's business, operations, drug products, drug product development, competition, and present and future business prospects. A reasonable investigation into the truthfulness and accuracy of the IPO Documents, including the statements incorporated by reference, would have revealed that the IPO Documents contained false and/or misleading statements and/or omitted material facts, as alleged herein. None of the Underwriter

Defendants made a reasonable investigation into the truthfulness and accuracy of the IPO Documents and are therefore primarily liable for the representations contained therein.

51. Each Defendant is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of BELLUS shares by disseminating materially false and/or misleading statements and/or concealing material adverse facts.

IV. CLAIMS ASSERTED IN THIS COMPLAINT

52. As discussed in detail below, Plaintiff asserts two separate sets of claims.

53. Counts One and Two assert securities fraud-based claims under §§ 10(b) and 20(a) of the 1934 Act and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder. In addition to BELLUS, the 1934 Act defendants include the Individual Defendants, Defendant Smith, and the Underwriter Defendants, (collectively, the “1934 Act Defendants”).

54. Plaintiff’s 1934 Act claims arise out of a fraudulent or deliberately reckless course of business conduct whereby, throughout the Class Period, the 1934 Act Defendants knew or recklessly disregarded that: (i) the statements and omissions they made, as alleged herein, were materially false and misleading; (ii) their statements would adversely affect the integrity of the market for BELLUS securities; and (iii) their statements would deceive investors into purchasing shares of BELLUS securities at artificially inflated prices, including in the Company’s \$70 million IPO which closed on September 9, 2019.

55. Specifically, the 1934 Act Defendants knowingly or recklessly made materially false and misleading public statements and/or omissions that: (i) BELLUS was struggling to enroll quality patients in its Phase 2 trial for BLU-5937; (ii) the low cough frequency threshold of 10 coughs per hour that BELLUS set for its Phase 2 trial resulted in a low number of severe cough patients being enrolled; (iii) as a result, BELLUS’s Phase 2 trial had failed to adequately account

for the correlation between higher cough frequency and higher efficacy that Merck’s studies had demonstrated; (iv) the design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy, which would cause the Company to fail the Phase 2 trial, to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales; and (v) as a result of the foregoing, Defendants’ positive statements about the Company’s business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

56. Counts Three, Four, and Five assert strict liability, non-fraud claims, under §§ 11, 12(a)(2) and 15 of the 1933 Act. The 1933 Act claims arise out of negligently made materially false and misleading statements and omissions in the Registration Statement and Prospectus (IPO Documents) issued in connection with the Company’s IPO. Plaintiff’s 1933 Act claims are not based on any allegation of deliberate or intentional misconduct, and Plaintiff expressly disclaims any reference or reliance upon fraud allegations for such claims. The 1933 Act Defendants include BELLUS, the Individual Defendants and the Underwriter Defendants (collectively, the “1933 Act Defendants”).

57. As set forth herein, each Defendant named under the 1933 Act claims negligently made materially false and misleading public statements and omissions in the IPO Documents that: (i) mischaracterized the Company’s ability to demonstrate efficacy in its Phase 2 trial of BLU-5937 by touting the efficacy demonstrated by the Merck’s Phase 2 trial of gefapixant without disclosing that the design of the Company’s Phase 2 trial was materially different from Merck’s and was resulting in a low number of severe cough patients being enrolled; (ii) negligently promoted inhibiting the P2X3 receptor as a “clinically validated treatment” based on Merck’s Phase 2 trials while disregarding, in designing the Company’s Phase 2 trial, the correlation

between high cough frequency and high efficacy that Merck's trials had demonstrated; and (iii) failed to adequately warn investors that certain "Risk Factors" listed in the IPO Documents had already materialized at the time of the IPO. At the time of the IPO, the Company's Phase 2 trial had failed to adequately account for the correlation between higher cough frequency and higher efficacy that Merck's studies had demonstrated. Thus, when the truth became known the Company would inevitably fail its Phase 2 trial, spend time and money on another Phase 2 trial, and fall further behind Merck, Bayer, and Shionogi in the race towards FDA approval and drug sales.

V. SUBSTANTIVE ALLEGATIONS

A. Relevant Background

58. Leading up to and throughout the Class Period, BELLUS concentrated its efforts on the development of its primary product candidate, BLU-5937, designed to be a highly selective antagonist of the P2X3 receptor, a purportedly clinically validated target linked to hypersensitivity. Specifically, BELLUS was focused on developing BLU-5937 to treat chronic cough and chronic pruritus (or chronic itch). BLU-5937 operated by targeting and inhibiting the P2X3 receptor.

1. The Treatment for Refractory Chronic Cough: An Unmet Need with a Multi-Billion Dollar Addressable Market

59. Cough is regulated by coordinated integration between airway sensory nerves, brainstem, and higher brain regions, enabling effective removal of irritants from the lower airways.⁴ However, it is possible for the cough reflex to become sensitized, leading to irresistible bouts of coughing triggered by exposure to relatively innocuous stimuli—for example, following a respiratory viral infection.

60. Chronic cough, defined as a cough lasting more than 8 weeks, is a clinical condition

⁴ Woo-Jung Song, Jin An, and Lorcan McGarvey, Korean Journal on Internal Medicine, *Recent progress in the management of chronic cough*, March 9, 2020.

that can be difficult to treat. Chronic cough affects an estimated 10% of the population, and about 50% of cases cannot be explained by other comorbidities, such as asthma or gastroesophageal reflux disease (*i.e.*, Refractory Chronic Cough (“RCC”)). Patients with chronic cough can experience impaired quality of life, interruption of activities of daily living, social isolation, anxiety, and depression.

61. Traditional pharmacologic treatments for chronic cough include nonprescription products and opiates.⁵ However, nonprescription products have not been considered any more effective than placebos when studied in randomized clinical trials for cough suppression, and the efficacy of opiates is not well supported in clinical trials. Further, opiates present severe safety risks, including respiratory depression, drowsiness, addiction, and accidental overdose. The lack of efficacy of traditional antitussive agents, combined with an improved understanding of the neurobiology of the cough reflex, has led to an increased focus on the development of new agents (such as BLU-5937) to address this treatment gap.

62. These new experimental chronic cough agents target specific receptors or channels in the peripheral sensory neurons. The goal is to reduce central nervous system adverse events (AEs) and control hypersensitivity, while reserving the protective cough response. Specifically, clinical studies have shown that the P2X3 receptors play an important role in the activation of sensory neurons integral to the cough reflex, making that receptor a promising therapeutic target in neuropathic conditions, such as RCC.

63. But there is still no FDA-approved P2X3 antagonist. Thus, a large opportunity exists for drug-makers that can obtain FDA approval for such a treatment.

⁵ Phung C. On, PharmD, BCPS, *Updates in Treatment of Adults with Chronic Cough*, AJMC (Oct. 15, 2020), <https://www.ajmc.com/view/updates-in-treatment-of-adults-with-chronic-cough> (last visited Sept. 15, 2021).

64. Indeed, there is a large target population for the treatment. Approximately 10% of the adult population in most developed countries, including the U.S., Europe, and Japan, suffers from chronic cough. In the U.S., that's 26 million patients, and the primary addressable market for BELLUS was approximately 10% of that population, or 2.6 million people, who have been treated for RCC for more than one year. Based on payer discussions and comparable product analysis, the Company estimated that the price of a treatment for RCC would be \$300-\$600 per month. Thus, there was a potential multi-billion-dollar market for the treatment of RCC.⁶

65. Of course, BELLUS (and any competing biotech companies) would have to successfully navigate and complete the FDA approval process for any new treatment.

2. The FDA Requires Submission of a New Drug Application Demonstrating Substantial Evidence that a Treatment is Effective

66. Enacted in 1938, the Food, Drug and Cosmetic Act (FDCA) created the FDA, an agency of the U.S. Department of Health and Human Services, to “protect the public health” by ensuring that “drugs are safe and effective.” 21 U.S.C. § 393(b)(2)(B). The FDCA provides that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with respect to such drug.” 21 U.S.C. § 355(a).

67. Accordingly, new pharmaceutical drugs, such as BLU-5937, must receive FDA approval prior to sale, marketing, and commercial distribution in the U.S. Drug sponsors (a.k.a., applicants), such as BELLUS, seek approval from the FDA through its New Drug Application (NDA) process. That process has been designed to provide information to permit the FDA to determine whether: (i) a drug is safe and effective in its proposed use(s), and the benefits of the

⁶ Jefferies London Healthcare Conference Corporate Presentation, BELLUS HEALTH, (Nov. 20, 2019), <https://www.jefferies.com/CMSFiles/Jefferies.com/files/BELLUS%20Health%20Inc.pdf>.

drug outweigh the risks; (ii) the drug's proposed labeling (package insert) is appropriate, and what it should contain; and (iii) the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve its identity, strength, quality and purity.⁷

68. In order to meet these standards, drug developers typically subject a drug candidate to a series of clinical trials designed to accumulate the data required to submit a successful NDA.

69. Clinical trials involve the administration of the drug to human subjects under the supervision of qualified clinical investigators.⁸ Each clinical trial protocol must be submitted to the FDA for clearance. Clinical trials are typically conducted in four sequential phases:

- **Phase I** involves researchers testing an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
- **Phase II** involves the experimental drug or treatment being given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III** involves the experimental drug or treatment being given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV** involves post-marketing studies, conducted after a drug or treatment is approved for use by the FDA, which provide additional information, including the treatment or drug's risks, benefits, and best use.

70. The FDA typically requires two successful clinical trials—which must be “adequate and well-controlled investigations”—in order for an applicant to provide “substantial evidence” that a drug is safe and effective. As such, clinical trials are conducted under strict

⁷ U.S. Food & Drug Admin., *New Drug Application (NDA)* (June 10, 2019), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

⁸ U.S. Food & Drug Admin., *What Are the Different Types of Clinical Research?* (Jan. 4, 2018), <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research>.

protocols detailing the objectives of the study, the parameters used in monitoring safety, and the effectiveness criteria to be evaluated.

71. Once the required clinical testing is successfully completed, the results of the preclinical and clinical studies are submitted to the FDA as part of an NDA to support approval to market a drug for one or more indications.

72. Within 60 days after submission, the FDA must conduct a preliminary review of an NDA to determine whether it is sufficiently complete to permit a substantive review. If the FDA accepts the NDA for filing, it begins the substantive review process, reviewing the NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packaged, and/or held meets standards designed to assure the product's continued safety, quality, and purity.

3. BELLUS's Successful Phase 1 Trial for BLU-5937

73. Prior to the Class Period, BELLUS had initiated healthy adult dosing in a Phase 1 clinical study of BLU-5937, the main objectives of which was to assess its safety, tolerability (including taste perception) and pharmacokinetic profile. In the Company's July 9, 2018 press release "announc[ing] the initiation of healthy subjects dosing in [that] Phase 1 clinical study," it specifically touted "two separate preclinical models" in which "BLU-5937 showed a significant reduction in cough and no taste loss side effect" in comparison to Merck's gefapixant⁹:

In a guinea pig cough model, BLU-5937 showed comparable anti-tussive efficacy to the current leading P2X3 antagonist in development, Merck & Co's gefapixant (also named AF-219 or MK-7264). In a rat taste model, BLU-5937 was not associated with taste loss whereas, consistent with clinical trial data previously presented by Merck & Co, gefapixant led to significant taste loss.

74. On November 19, 2018, BELLUS announced positive top-line results from its

⁹ *BELLUS Health Initiates Phase 1 Clinical Study for its Chronic Cough Drug Candidate, BLU-5937*, BELLUS HEALTH INC. (July 9, 2018), <https://ir.bellushealth.com/node/6336/pdf>.

Phase 1 clinical study of BLU-5937, demonstrating a good safety and tolerability profile as well as a pharmacokinetic profile supporting twice-a-day (“BID”) dosing.¹⁰ Most notably, at the anticipated therapeutic doses of 50 to 100 mg, BLU-5937 did not cause any loss of taste perception; only 1 out of 24 subjects reported transient taste alteration. Based on this data, the Company intended to advance BLU-5937 into a Phase 2 clinical study beginning in mid-2019.

75. The FDA accepted the Company’s Investigational New Drug (“IND”) application on April 30, 2019, clearing it to start its Phase 2 clinical study of BLU-5937 for patients with chronic cough in the U.S. In the Company’s press release announcing clearance of that IND, Defendant Bellini is quoted as touting that “[u]nlike other P2X3 antagonists, BLU 5937 is highly-selective, meaning that it can potentially reduce coughing with very little to no effect on taste.”¹¹

4. BELLUS’s Competitors Successfully Complete Their Phase 2 Trials Before BELLUS Even Begins Enrolling Patients in its Phase 2 Trial

76. In addition to BLU-5937, leading investigative P2X3 antagonists include: (1) Merck’s gefapixant (AF-219 or MK-7264); (2) Shionogi’s sivopixant (S-600918); and Bayer’s eliapixant (BAY-1817080).

77. Merck entered the race towards FDA approval of a P2X3 antagonist by acquiring Afferent Pharmaceuticals, the developer of AF-219, now known as gefapixant (or MK-7264), in June 2016. MK-7264 is an orally administered, non-narcotic, P2X3 receptor antagonist, with a P2X3 vs. P2X2/3 selectivity rating of 2-7x. At the time of Merck’s acquisition, AF-219 was being

¹⁰ *BELLUS Health Announces Positive Top-Line Phase 1 Results for its Chronic Cough Drug Candidate BLU-5937*, BELLUS HEALTH INC. (Nov. 19, 2018), <https://ir.bellushealth.com/node/6301/pdf>.

¹¹ *BELLUS Health Announces Clearance of U.S. IND for BLU-5937 Phase 2 Study in Chronic Cough Patients*, BELLUS HEALTH INC. (Apr. 3, 2019), <https://ir.bellushealth.com/node/6276/pdf>.

evaluated in a Phase 2b clinical trial for the treatment of Refractory Chronic Cough (RCC).¹² The study was comprised of two cohorts; data on cough frequency from the first cohort, designed to explore higher doses of AF-219, was presented at the 2016 American Thoracic Society International Conference on May 18, 2016.¹³ Data from the second cohort of the Phase 2b study, which evaluated lower doses of AF-219 (as low as 7.5mg), was to be presented at a medical/scientific conference in the second half of 2016.

78. The Phase 2b trial was a randomized, double-blind, placebo-controlled, crossover, dose escalation study with two 16-day treatment periods and a 3–7-day washout. Each patient in the first cohort of Phase 2b was treated with AF-219 or matching placebo, with a dose-escalation occurring every 4 days at 50 mg, 100mg, 150mg and 200mg BID, consecutively, and then crossed over to the other treatment arm. Each treatment arm thus compromised 16 days. The lowest dose of 50mg BID was shown to have similar efficacy as the previously evaluated dose of 600mg BID during Afferent's Phase 2 trial—randomized, double-blind, placebo-controlled study in patients with RCC, where patients were treated for 2 weeks and crossed-over after a 2-week washout.¹⁴ An analysis of responders on the 50 mg dose showed nearly half of patients had at least a 50%

¹² ClinicalTrials.gov, *A Dose Escalation Study of Gefapixant (AF-219/MK-7264) in Refractory Chronic Cough (MK-7264-010)* (Jan. 28, 2015 updated Oct. 22, 2020), <https://clinicaltrials.gov/ct2/show/study/NCT02349425>.

¹³ *Afferent Pharmaceuticals Presents Updated Positive Results with AF-219 from Phase 2B Chronic Cough Study at the 2016 American Thoracic Society (ATS) International Conference*, BUSINESS WIRE (May 16, 2016, 12:00 PM EDT), <https://www.businesswire.com/news/home/20160516005407/en/Afferent-Pharmaceuticals-Presents-Updated-Positive-Results-with-AF-219-from-Phase-2B-Chronic-Cough-Study-at-the-2016-American-Thoracic-Society-ATS-International-Conference>.

¹⁴ ClinicalTrials.gov, *A Study to Assess the Efficacy of Gefapixant (MK-7264/AF-219), in Participants With Chronic Cough (MK-7264-006)* (EPICC) (Sept. 13, 2011 updated Nov. 24, 2020), <https://clinicaltrials.gov/ct2/show/NCT01432730?term=Afferent+Pharmaceuticals%2C+Inc.&draw=2&rank=5>.

reduction in cough frequency, and 35% of patients had at least a 70% reduction in cough frequency.

79. Eligible patients enrolled in the Phase 2b trial had chronic cough for at least a year, a negative chest radiograph, and a Cough Severity Visual Analog Scale (VAS) score greater than or equal to 40mm. Certain exclusion criteria, such as current or past smokers, applied. Awake cough was measured with an ambulatory cough monitor (VitaloJAK). The primary efficacy assessment was the reduction in awake cough frequency compared to placebo. Safety and tolerability were also evaluated.

80. Results from the first cohort of Phase 2b were compiled from 10 centers in the U.S., enrolling 29 patients. Women with a mean age of 63 years comprised 86% of patients; median cough duration was 15 years; *the mean awake cough frequency was 56.9 coughs per hour at baseline*; cough severity VAS was 58mm; and sleep cough frequency was 7.9 coughs per hour. Patients treated with AF-219 at all 4 doses demonstrated significant reduction in awake cough frequency compared to placebo, with all doses showing equivalent efficacy. As in prior studies, a change in taste acuity was the most common adverse event (AE), was dose-dependent, and led to study discontinuation by one patient. Nonetheless, Afferent concluded that AF-219 treatment in patients with chronic cough resulted in a clinically important reduction in awake cough frequency compared to placebo, and efficacy was maintained at lower doses which were well-tolerated.

81. Then, at the American Thoracic Society 113th Annual Conference on May 22, 2017, Merck announced the results of a second, larger Phase 2b trial.¹⁵ The randomized, double-blind, placebo-controlled, parallel group study evaluated MK-7264 (formerly AF-219) in 253

¹⁵ Merck & Co., Inc., *Merck Announces Presentation of Phase 2 Results for MK-7264, an Investigational, P2X3 Receptor Antagonist, Being Evaluated for the Treatment of Chronic Cough* (May 22, 2017, 10:20 AM ET), <https://www.merck.com/news/merck-announces-presentation-of-phase-2-results-for-mk-7264-an-investigational-p2x3-receptor-antagonist-being-evaluated-for-the-treatment-of-chronic-cough/> (last visited Sept. 17, 2021).

patients with RCC (chronic cough for over one year).¹⁶

82. Eligible patients were defined in the study protocol as having RCC based on American College of Chest Physicians (ACCP) and British Thoracic Society (BTS) guidelines. As such, patients were considered to have RCC if they had a clinical evaluation that identified at least one comorbid condition associated with chronic cough but continued to cough despite receiving appropriate diagnostic workup and at least 2 months of therapy for the comorbid condition(s); or if patients presented no objective evidence of a comorbid condition associated with chronic cough despite appropriate diagnostic workup per ACCP and BTS guidelines.¹⁷

83. Additional inclusion criteria were age limits from 18 to 80 years and cough severity score of greater than or equal to 40mm cough severity VAS at screening. Certain exclusion criteria, such as current or recent smokers within 6 months of enrollment, applied.

84. Results from the Phase 2b trial demonstrated that most patients were female (76%), white (92%), never smokers (70%), a median age of 61 years, and on average, overweight. All enrolled patients were from the U.S. or United Kingdom. Although eligibility criteria required a cough lasting for at least one year, patients' median cough duration was much longer at 11 years. And while the eligibility criteria did not specify an awake cough frequency threshold, the median awake cough frequency was 28.9 coughs per hour, ranging from less than 1 to over 700 coughs per hour, *with a mean awake cough frequency of 40.3 coughs per hour* (standard deviation 55.8).

85. Equal groups of enrolled patients were randomized to receive placebo (n=63), 7.5

¹⁶ ClinicalTrials.gov, *A 12-Week Study in Participants With Refractory Chronic Cough (MK-7264-012)* (Nov. 24, 2015 updated June 30, 2020),

<https://clinicaltrials.gov/ct2/show/NCT02612610?term=Afferent+Pharmaceuticals%2C+Inc.&draw=2&rank=1> (last visited Sept. 17, 2021).

¹⁷ January 25, 2021, Characterization of Patients with Refractory or Unexplained Chronic Cough Participating in Phase 2 Clinical Trial of the P2X3-Receptor Antagonist Gefapixant.

mg (n=63), 20 mg (n=63), and 50 mg (n=63) doses of MK-7264 twice daily. The primary efficacy endpoint was the mean change in awake cough frequency after 12 weeks of treatment vs. baseline. Cough frequency was measured using sound recordings obtained by a digital recording device. Patients who received a 7.5mg, 20mg and 50mg dose of MK-7264 experienced a reduction in awake cough frequency from baseline compared to placebo of 22%, 22% and 37%, respectively; the difference for the 50mg dose compared to placebo was statistically significant (p<0.05). The secondary endpoint of patient-reported cough severity (0-100mm on the VAS) compared to baseline showed a reduction of 15.2mm for placebo, 19.2mm for 7.5mg, 23.4mm for 20mg and 31.1mm for 50mg doses.

86. Dysgeusia, an alteration in taste, was the most common AE reported in 4.8%, 9.5%, 33.3% and 47.6% of patients receiving placebo, 7.5mg, 20mg, and 50mg of MK-7264, respectively. Hypogeusia, reduced ability to taste, was reported in 1.6%, 0%, 17.5% and 23.8% of patients on placebo, 7.5mg, 20mg, and 50mg of MK-7264, respectively. One patient in the placebo group and six patients in the 50mg treatment group discontinued due to taste-related AEs. No patients in the 7.5mg and 20mg groups discontinued due to taste-related AEs.

87. On the basis of these Phase 2b trials, Merck began its Phase 3 trials on March 14, 2018 (COUGH-1 and COUGH-2). COUGH-1 and COUGH-2 were international, randomized, double-blind, placebo-controlled, pivotal studies to evaluate the efficacy and safety of gefapixant (age > 18 years; cough duration > 1 year; Cough Severity VAS score > 40mm). In both studies, patients were randomized to one of three dosage groups: placebo, 15mg, or 45mg. COUGH-1 had a 40-week extension period, while COUGH-2 had a 28-week extension period.

88. Shionogi was not far behind Merck. On March 14, 2019, Shionogi published top-line data from its Phase II study (Japan only) assessing the tolerability and efficacy of S-600918

(later known as sivpixant), a P2X3 antagonist with a selectivity rating of ~250x.¹⁸ The multi-center, randomized, double-blind, placebo-controlled, crossover study was conducted on 31 patients with refractory/unexplained chronic cough lasting 6 months or longer.¹⁹ While a therapeutic dose was not specified, the efficacy and safety of S-600918 was evaluated with once-daily administration for two weeks.

89. The primary endpoint was the rate of change in hourly cough frequency during the daytime from the baseline to two weeks after administration of S-600918. Phase II data showed the change in the rate to be 54.1%, while the placebo was 33.0%; the rate of change of S-600918 adjusted by placebo from the baseline accounted for 31.6% ($p=0.0546$). As one of the secondary endpoints, the rate of change adjusted by placebo in hourly cough frequency 24 hours after S-600918 administration from the baseline stood at 30.9%, which demonstrated a statistically significant decrease ($p=0.0386$). Shionogi did not publish taste-related AEs other than it was “lower than the competitor”, which analysts took to mean that S-600918 had less of a taste-effect than Merck’s gefapixant but more than BELLUS’s BLU-5937 in its Phase 1 trial.²⁰ Regarding the change in scores from the baseline of the Leicester Cough Questionnaire (LCQ) that assesses quality of life (QOL) specific to cough, S-600918 showed significant improvement compared with the placebo administration ($p=0.0415$).

90. After the release of Shionogi’s Phase II results, a May 2, 2019 analyst report noted that, “[w]hile there are many unanswered questions surrounding the asset, its efficacy

¹⁸ Shionogi & Co., Ltd., *Research and Development at Shionogi* (Mar. 14, 2019), https://www.shionogi.com/content/dam/shionogi/global/investors/pdf/e_p190314.pdf.

¹⁹ Shionogi & Co., Ltd., *Congress Presentation on Clinical Study of S-600918, a Drug Candidate for the Treatment of Refractory/Unexplained Chronic Cough* (Oct. 2, 2019), https://www.shionogi.com/content/dam/shionogi/global/news/pdf/2019/e_191002.pdf.

²⁰ LifeSci Capital LLC, Alpha Series, *Bellus Health (BLU.TO): Data from Shionogi’s S-600918 Highlights Efficacy of a Selective P2X3 Antagonist in Chronic Cough* (May 2, 2019).

demonstrates the potential of a selective P2X3 antagonist and sheds light on the role of P2X3 as a prominent driver in chronic cough. In regards to Bellus's BLU-5937, given its enhanced selectivity compared to every other P2X3 antagonist in development, the S-600918 results provide additional support for the asset to significantly reduce cough while having the least amount of taste disturbances of the P2X3 antagonists in clinical development.”²¹ The report added: “[w]hile it’s difficult to know exactly how BLU-5937 will compare to S-600918 and gefapixant without more clinical data, multiple cough experts that we consulted mentioned that even if it is less effective than gefapixant, the taste advantage would still be appealing for many patients.”

91. At the same time, Bayer had been developing the selective P2X3 antagonist with a selectivity rating of 25-125x, BAY-1817080 (later known as ellapixant), in collaboration with Evotech. On July 25, 2019, Evotech announced that BAY-1817080 had met all endpoints in a Phase I/II study for RCC, including the study’s primary endpoint, a reduction in 24-hour cough frequency.²² The study was designed to evaluate four ascending oral doses of BAY-1817080 in healthy volunteers and chronic cough patients.²³

92. With the release of positive results from Bayer’s Phase II trial, analysts at LifeSci Capital speculated that, “[w]hile no details have been presented about the extent of the cough reduction or the asset’s effect on taste, positive results from this study, as well as Shionogi’s Phase IIa data with S-600918, help solidify the potential of a selective P2X3 antagonist and have direct

²¹ LifeSci Capital LLC, Alpha Series, *Bellus Health (BLU.TO): Data from Shionogi’s S-600918 Highlights Efficacy of a Selective P2X3 Antagonist in Chronic Cough* (May 2, 2019).

²² Evotec, *Evotec SE: P2X3 antagonist demonstrates efficacy against refractory chronic cough in Phase II (POC)* (July 25, 2019), <https://www.evotec.com/en/invest/news-announcements/press-releases/p/evotec-se-p2x3-antagonist-demonstrates-efficacy-against-refractory-chronic-cough-in-phase-ii-poc-5837> (last visited Sept. 17, 2021).

²³ LifeSci Capital LLC, Alpha Series, *Bayer’s Selective P2X3 Asset Hits on All Endpoints in Phase I/II Chronic Cough Study, Adding Validation to the Selective Approach* (July 25, 2019).

readthrough to Bellus' BLU-5937." *Id.* "Based on our conversations with KOLs, we believe that BLU-5937 has the potential to be a best-in-class product given its selectivity (~1500x compared to 2-7x with Merck's gefapixant and 25-125x with Bayer's [BAY-1817080])." *Id.*

93. Similarly, in an August 9, 2019 report discussing the progression of P2X3 studies, analysts at Mackie Research noted that the recently disclosed positive results from Bayer's Phase II trial combined "[w]ith previously disclosed P2X3 data from Merck (for gefapixant) and Shionogi (for S-600918), as well as, recent setbacks of other drug classes (NK1 antagonists, TRP channel modulators and a7 nAChR agonists), we believe P2X3 inhibitors represent the most promising and advanced drug class for treating chronic cough. We also believe BLU-5937 could be the best in class due to its ultra-high selectivity toward P2X3."²⁴

B. Defendants' Touting of Competitors' Clinical Trials Concealed Design Flaws in BELLUS's Phase 2 Trial and Allowed BELLUS to Successfully Raise Capital

1. Defendants Generated Investor Interest in the IPO by Capitalizing on Competitors' Clinical Studies and Strengthening its Management Team

94. As detailed above, a proof-of-concept study conducted by Merck showed dramatic effects on objective cough frequency, cough severity, and cough-specific quality of life, suggesting that the P2X3 receptor was an integral part of the cough hypersensitivity pathway. However, almost all patients developed taste disturbance during treatment with Merck's gefapixant, which is now attributed to the consequential effect on P2X2/3 channels.

95. As a result, although BELLUS was behind its competitors in clinical development, it was able to distinguish itself and generate investor excitement for BLU-5937 in advance of its

²⁴ Mackie Research Capital Corp. – *BELLUS HEALTH INC: Expanding Indications for BLU-5937 – Q2 Results* (Aug. 9, 2019).

IPO. While implying efficacy through its competitors' successful clinical studies, BELLUS focused on its high P2X3 selectivity (~1500x) and lack of the taste disturbance side effect.

96. For example, in its July 30, 2019 press release announcing that the Company had enrolled the first patient in its Phase 2 (RELIEF) study of BLU-5937, BELLUS noted that “[t]he P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it has been validated in multiple clinical studies. With a modestly-selective P2X3 antagonist therapy for chronic cough, an adverse effect on taste perception is a well-known and widely-documented tolerability issue.”²⁵ In addition, Defendant Bellini was quoted as stating that “[t]he RELIEF study in chronic cough will build on the body of earlier clinical evidence which showed, for the first time, that a highly-selective P2X3 antagonist is associated with little to no impact on taste.” *Id.*

97. The press release also confirmed that “[t]he RELIEF study [wa]s a dose-escalation, placebo-controlled, and crossover design to assess the efficacy, safety, and tolerability of BLU-5937, a highly selective P2X3 antagonist, at four doses; 25, 50, 100 and 200 mg, administered orally, twice daily (BID). Approximately 65 patients with refractory chronic cough are expected to be enrolled at twelve clinical sites in the United Kingdom and United States.” *Id.*

98. In order to have a successful study, and remain competitive in the race towards FDA approval, it was critical that BELLUS learn from its competitors' prior clinical studies and utilize that data in the design of BELLUS's RELIEF study. After all, by the time the Company began enrolling patients in its Phase 2 study, its competitors had initiated and/or completed their P2X3 antagonist Phase 2 studies. Because Merck's clinical studies had shown the correlation between high cough counts and high efficacy, the Company knew or should have known that

²⁵ BELLUS Health Inc., *BELLUS Health Announces First Patient Enrolled in Phase 2 Study of BLU-5937 for the Treatment of Refractory Chronic Cough & Pursuit of Second Indication in Chronic Pruritus* (July 30, 2019), <https://ir.bellushealth.com/node/6246/pdf>.

enrolling patients with higher cough counts would increase the chances of demonstrating efficacy in its Phase 2 trial. Fortunately for the Individual Defendants and Defendant Smith, they knew or had access to the cough frequency of the patients being enrolled in the RELIEF study.

99. To support the RELIEF study, and generate investor interest in advance of the IPO, BELLUS hired Defendant Bonuccelli. The Company announced her appointment as CMO on August 26, 2019, boasting that she was bringing “over 20 years of pharmaceutical experience with significant expertise in clinical and product development of respiratory and non-respiratory products.”²⁶ Also in the press release, Defendant Bellini declared that “Dr. Bonuccelli has the ***ideal scientific and product development background*** to help advance the study of BLU-5937 for the treatment of chronic cough” and the Company would be “leveraging her ***deep proficiency in respiratory diseases***, and her ***substantial development expertise in bringing compounds through the clinical development lifecycle***, in order to fulfill our mission of helping patients overcome the burden of chronic cough.”

2. BELLUS Successfully Completes its IPO

100. Because BELLUS did not (and still does not) have any revenue generating products on the market, it decided to raise capital from investors in order to finance its business, generally, and to continue funding the research and development costs of BLU-5937, specifically. Leading up to and through the IPO, the 1934 Act Defendants were able to generate and maintain intense investor excitement by presenting BLU-5937 as poised to dominate the untapped ~\$10 billion market for chronic cough – riding the coattails of competitors.

101. On September 3, 2019, while in the middle of its Phase 2 study, BELLUS

²⁶ BELLUS Health Inc., *BELLUS Health Strengthens Leadership Team with Appointment of Dr. Catherine Bonuccelli, MD as Chief Medical Officer* (Aug. 26, 2019), <https://ir.bellushealth.com/node/6951/pdf>.

announced the filing of a preliminary prospectus supplement (the “Supplement”) to its short form base shelf prospectus dated July 26, 2019 (the “Base Prospectus”) in connection with a proposed \$60 million IPO of its common shares, as well as the filing of an application to list its common shares on the NASDAQ in the U.S. under the ticker “BLU.”²⁷ The Supplement and accompanying Base Prospectus were also filed with the SEC as part of a registration statement on Form F-10 (the “Registration Statement”), in accordance with the Multijurisdictional Disclosure System (“MDS”) established between Canada and the US. The Company intended to use the net proceeds of the IPO primarily to fund research and development activities, general and administrative expenses, working capital needs, and other general corporate purposes.

102. On September 5, 2019, BELLUS filed with the SEC its final amendment to the Registration Statement, constituting the Prospectus for the IPO (together with the Registration Statement, the “IPO Documents”). The IPO Documents misleadingly conveyed to investors that the Company’s Phase 2 RELIEF study followed the same design and parameters as Merck’s successful clinical studies of gefapixant, which had demonstrated efficacy. The IPO Documents touted that, because BLU-5937 was more selective than its competitors, the Company’s Phase 2 study would show that the drug was safer and/or more tolerable – *i.e.*, it would not have a taste loss or alteration side effect.

103. As a result, the IPO was well-received by investors. By the time the IPO closed on September 9, 2019, BELLUS had raised \$70 million – \$10 million more than initially planned.

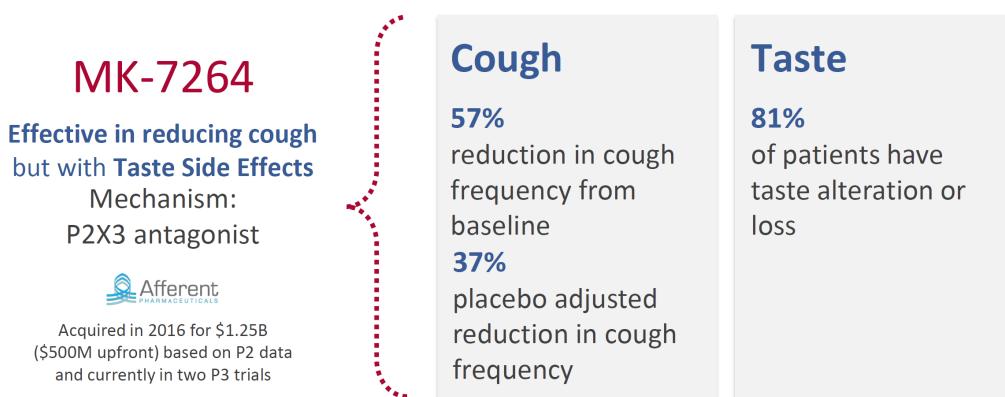
²⁷ BELLUS Health Inc., *BELLUS Health Announces the Launch of a US\$60 Million Public Offering of Common Shares in Canada and the United States and the Filing of an Application to List Its Common Shares on Nasdaq* (Sept. 3, 2019), <https://ir.bellushealth.com/node/6986/pdf>.

3. Throughout the Class Period, Defendants Continued to Mislead Investors about BELLUS's Phase 2 Trial by Likening it to Competitors' Trials

104. Leading up to and throughout the Class Period, despite being well aware that Merck, Bayer and Shionogi were ahead of BELLUS in the clinical path towards obtaining FDA approval, Defendants assured investors that the Company was on the same clinical development timeline and that BLU-5937 would come with a better safety and/or tolerability profile. Defendants stressed that BLU-5937 was the most selective drug and thus would not have the AEs of taste alteration or loss of taste. As a result, investors were misled into believing that the RELIEF study would ultimately demonstrate a higher level of safety or tolerability with the same or higher level of efficacy as Merck's gefapixant, Bayer's eliapixant, and Shionogi's sivopixant.

105. BELLUS specifically utilized Merck's Phase 2b results to demonstrate to investors that the P2X3 antagonist mechanism worked against RCC, albeit with a cost in the form of a taste loss or alteration AEst²⁸:

Proof-of-Mechanism Established by First-in-Class P2X3 Antagonist MK-7264



106. BELLUS also implied the relevance of its competitors' clinical development by

²⁸ *Jefferies London Healthcare Conference Corporate Presentation*, BELLUS HEALTH, (Nov. 20, 2019), <https://www.jefferies.com/CMSFiles/Jefferies.com/files/BELLUS%20Health%20Inc.pdf>, at 10; Presentation of BELLUS Health, Cowen 40th Annual Health Care Conference (Mar. 3, 2020), <https://ir.bellushealth.com/static-files/c332483c-a1e2-45e3-805e-d33c4c95a7c5>.

keeping investors apprised of their status and milestones. For example, the Company's presentation at the Jefferies London Healthcare Conference on November 20, 2019 ("Jefferies Presentation") highlighted the following "Competitor catalysts" as part of the future "12 Months Milestones" for BELLUS:²⁹

- Shionogi Phase 2 data
- Bayer Phase 2 data
- Merck MK-7264 pipeline: Phase 2 in endometriosis pain

107. Similarly, BELLUS included the following "Competitor catalysts" among the "Key Anticipated Milestones Over Next 12 Months" in its presentation at the Cowen 40th Annual Health Care Conference on March 3, 2020 ("Cowen Presentation"):³⁰

- Bayer Phase 2 data (1H)
- Merck MK-7264: Phase 2 data in endometriosis pain (1H)
- Merck MK-7264 Phase 3 data in chronic cough (2H)

108. And BELLUS's presentation at its Health Chronic Cough Virtual KOL Meeting on May 27, 2020 ("KOL Presentation") included the "Competitive Landscape – Development Path":

 MERCK MK-7264 Phase 3: COUGH-1 and COUGH-2 Trials <ul style="list-style-type: none"> • ~2000 patients in two Phase 3 trials (COUGH-1 and COUGH-2) • 45 mg BID hit primary efficacy endpoint; 15 mg BID did not • Safety and tolerability profile "consistent with the previously reported Phase II studies" <small>https://investors.merck.com/news/press-release-details/2020/Merck-Announces-Top-Line-Results-from-Phase-3-Trials-Evaluating-Gefapitant-an-Investigational-Treatment-for-Refractory-or-Unexplained-Chronic-Cough/default.aspx</small>	 SHIONOGI S-600918: Dose Ranging Phase 2b Trial <ul style="list-style-type: none"> • 372 patients across 4 arms; 4 week treatment duration • 3 active doses: 50mg, 150mg and 300mg QD • Geography: US, EU and Japan • Trial start in Q1 2020 <small>https://clinicaltrials.gov/ct2/show/NCT04110054</small>	 BAY 1817080: Dose Ranging Phase 2b Trial <ul style="list-style-type: none"> • 236 patients across 4 arms; 12 week treatment duration • 3 active BID doses • Geography: US and EU • Trial start in Q2 2020 <small>https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-004169-42/NL</small>
<ul style="list-style-type: none"> • Estimated to be approved in US in 2022¹ 	<ul style="list-style-type: none"> • Estimated to start Phase 3 in 2022¹ 	<ul style="list-style-type: none"> • Estimated to start Phase 3 in 2022¹

BLU-5937 well-positioned with potential Phase 3 start in 2021 or early 2022



¹Bellus estimate; not sponsor statement

42

²⁹ *Jefferies London Healthcare Conference Corporate Presentation*, BELLUS HEALTH, (Nov. 20, 2019), <https://www.jefferies.com/CMSFiles/Jefferies.com/files/BELLUS%20Health%20Inc.pdf>.

³⁰ Presentation of BELLUS Health, *Cowen 40th Annual Health Care Conference* (Mar. 3, 2020) <https://ir.bellushealth.com/static-files/c332483c-a1e2-45e3-805e-d33c4c95a7c5>.

4. As BELLUS's Competitors Released More Data Throughout the Class Period, the Market Reacted Positively in Anticipation of RELIEF Results

109. Because the Company continually likened its Phase 2 RELIEF trial to its competitors' clinical trials throughout the Class Period, the market followed and reacted positively to positive data from those clinical trials.

110. On September 22, 2019, LifeSci Capital reported that abstracts for the European Respiratory Society (ERS) were released the prior weekend, including Phase II results for Shionogi's S-600918.³¹ Through this abstract, the public learned that the previously disclosed statistically significant change in cough frequency was achieved at a baseline cough frequency of *56 coughs per hour*.³² The abstract also included new information regarding the incidence of AEs seen in the Phase II study—35.5%, compared to 29.0% with the placebo, which showed no significant difference. The incidence of taste disturbance AEs was 6.5% after administration of S-600918. The only therapeutic dose of S-600918 tested during the Phase II trial was 150 mg dose and so questions remained around PK/PD and what the taste effect was with other doses used in its prior study. As noted in the analyst report, the new information showed that the “overall incidence of treatment adverse events (AEs) was not significantly different between the two treatments [(comparing S-600918 to Merck’s gefapixant)].” That said, the analyst report stated, “the taste effect was less than most expected, including us.”

³¹ LifeSci Capital LLC, Alpha Series, *Bellus Health: ERS Abstract from P2X3 Competitor Shionogi Results Continue to Support a Selective P2X3 Approach, Although Taste Effect with S-600918 is Less than Expected* (Sept. 22, 2019).

³² Akio Niimi, Hiroyuki Ishihara, Hideaki Hida, Sayaka Miyazaki, European Respiratory Journal, 2019, 54 Suppl. 63, RCT452; DOI: 10.1183/13993003.congress-2019.RCT452, “Late Breaking Abstract - Phase 2a randomised, double-blind, placebo-controlled, crossover study of a novel P2X3 receptor antagonist S-600918 in patients with refractory chronic cough”. As noted by BELLUS in later presentations, Shionogi did not disclose if this baseline was an arithmetic or geometric mean but was nevertheless known as of September 2019. See BELLUS Investor Presentation (September 11, 2020) at p.17, n. 2-3.

111. Given these results, Shionogi moved forward with a placebo-controlled, dose-finding Phase IIb study in 372 patients with refractory chronic cough.³³ Participants received 50, 150, or 300mg of S-600918 once a day for 28 days and their change in cough frequency was assessed via a cough monitor. Shionogi's Phase IIb trial began in late February 2020 and completed in late May 2021.

112. In the same LifeSci Capital report, analysts provided their thoughts on how the Shionogi Phase 2 data pertained to BELLUS's BLU-5937, providing in relevant part:

Results support that P2X3 is a key driver of chronic cough, which is good for BLU-5937. The exact role of P2X2/3 inhibition and the resulting taste alterations on cough aren't 100% known yet given limited data from the more selective P2X3 antagonists, but it appears to be between none and low given similar efficacy seen with the less selective gefapixant.³⁴

113. On March 17, 2020, Merck announced its top-line efficacy results from its two pivotal Phase 3 trials. In these studies, the primary efficacy endpoints were met for the gefapixant 45mg twice daily treatment arms – demonstrating a statistically significant decrease in 24-hour coughs per hour versus placebo at 12 (COUGH-1) and 24 weeks (COUGH-2). The gefapixant 15mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 trial. The doses of 45mg and 15mg were selected based on the data collected from Merck's Phase 1 and Phase 2 studies. In COUGH-1, there was an 18% reduction compared to placebo on the higher dose, while COUGH-2 resulted in just under a 15% reduction at the same dose.

114. Of the 732 patients enrolled in COUGH-1, 74% were female with a mean age of 59 years and mean baseline cough duration of 11.5 years. In COUGH-2, consisting of 1,317 patients,

³³ LifeSci Capital LLC, Alpha Series, *Bellus Health: More Clarification Surrounding S-600918's ERS Data and Phase IIb Study Design* (Oct. 17, 2019).

³⁴ LifeSci Capital LLC, Alpha Series, *Bellus Health: ERS Abstract from P2X3 Competitor Shionogi Results Continue to Support a Selective P2X3 Approach, Although Taste Effect with S-600918 is Less than Expected* (Sept. 22, 2019).

75% were female with a mean age of 58 years, and mean cough baseline duration of 11.1 years. The safety and tolerability profile of gefapixant during COUGH-1 and COUGH-2 to date were consistent with the previously reported Phase 2b trials. The incidence of serious AEs was similar between treatments, at under 4%.

115. With the release of Merck's COUGH-1 and COUGH-2 data, Guggenheim Securities issued an analyst report titled “BLU (Buy) – MRK Phase 3 Gefapixant Data Positive for BLU and More Selective P2X Agents”, noting that “this data [i]s a best case outcome for [BELLUS] and the most selective P2X agents, as [Merck] was able to scale and successfully run a large and longer duration Ph.3 study, while the 15mg dose failing removes what could have been a more tolerable dose for patients.”³⁵

116. Evidencing that the market used Merck's clinical studies as a barometer for BELLUS, the Company's shares rose almost 11% after Merck released top-line efficacy results from COUGH-1 and COUGH-2 on March 17, 2020.³⁶

117. On April 1, 2020, the American Thoracic Society published the International Conference Abstracts, including additional information regarding the safety and efficacy of BAY-1817080 observed in its Phase 2 trial.³⁷ To investigate the safety, tolerability and efficacy of BAY-

³⁵ Guggenheim Securities, LLC, *BLU (Buy) – MRK Phase 3 Gefapixant Data Positive for BLU and More Selective P2X Agents*, (Mar. 17, 2020).

³⁶ Phil Taylor, *Merck's chronic cough drug gefapixant clears phase 3 test*, PHARMAPHORUM TM (Mar. 18, 2020) <https://pharmaphorum.com/news/mercks-chronic-cough-drug-gefaxant-clears-phase-3-test/>; *Merck Announces Top-Line Results from Phase 3 Trials Evaluating Gefapixant, an Investigational Treatment for Refractory or Unexplained Chronic Cough*, BUSINESS WIRE (Mar. 17, 2020, 06:45 AM ET), <https://www.businesswire.com/news/home/20200317005183/en/Merck-Announces-Top-Line-Results-Phase-3-Trials>.

³⁷ ATS Journals, *Safety and Efficacy of BAY 1817080, a P2X3 Receptor Antagonist, in Patients with Refractory Chronic Cough (RCC)*, https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2020.201.1_MeetingAbstracts.A7648 (last visited September 17, 2021).

1817080 in patients with RCC, the Phase 2 study enrolled 40 adult nonsmokers with RCC for more than one year, unresponsive to more than 8 weeks targeted treatment for identified underlying triggers, or with no trigger identified (unexplained chronic cough).³⁸ The Phase 2 trial was designed as a 2-way crossover, double-blind, placebo-controlled, randomized study, administering orally, BAY-1817080 twice-daily at a dosage of 10, 50, 200 and 750mg (7 days at each dosage) and matched placebo.

118. Higher doses of BAY-1817080 decreased 24-hour cough counts with a mean relative reduction vs placebo: 50 mg, 15% ($P = .054$); 200 mg, 23% ($P = .004$); and 750 mg, 25% ($P = .002$). With placebo, cough counts fell from baseline by 17% ($P = .025$). BAY-1817080 also significantly improved patient-reported cough severity at doses ≥ 50 mg.

119. However, researchers found that AEs occurred in 41-49% of patients who received BAY-1817080 and 65% of patients who received placebo, though most were considered mild. A taste-related AE was seen in 5%, 10%, 15% and 21% of patients who received 10, 50, 200, 740mg of BAY-1817080, respectively, and in 3% of patients who received placebo.

120. Likewise, on April 1, 2020, Shionogi released an abstract for its Phase II study focused on health-related quality of life endpoints.³⁹ Estimated changes in cough severity VAS from baseline was -18.8 mm for patients receiving S-600918 and -12.4 mm for placebo (difference was -6.4 with $p=0.1334$). Regarding quality-of-life changes measured by the EQ-5d-5L (Japanese version of EuroQol-5 dimensions-5 levels) and the Leicester Cough Questionnaire, Shionogi reported the difference in total scores were 0.09 ($p=0.0082$) and 1.40 ($p=0.0415$), respectively,

³⁸ ClinicalTrials.gov, *Repeat Doses of BAY 1817080 in Healthy Males & Proof of Concept in Chronic Cough Patients* (Oct. 16, 2017, updated July 18, 2019), <https://clinicaltrials.gov/ct2/show/NCT03310645> (last visited Sept. 17, 2021).

³⁹ Guggenheim Securities, LLC, *BLU (BUY) Unpacking ATS Abstracts – BAY'1817080 Data Underwhelming; Improves Position for BLU* (Apr. 1, 2020).

between S-600918 and placebo, both in favor of S-600918. For Patient Global Impression of Change, 23 patients (74.2%) receiving treatment rated themselves very much improved, much improved, or minimally improved, as compared to only 17 patients (54.8%) receiving placebo. Further, the April 1, 2020 abstract revealed that the Phase II trial reported ~7% taste AEs at the 150mg dosage.

121. Guggenheim Securities published an analyst report on April 1, 2020 titled “BLU (Buy): Unpacking ATS Abstracts – BAY’1817080 Data Underwhelming; Improves Position for BLU”, noting that based on their analysis of the abstracts released by Bayer, “this [i]s a positive for [BELLUS] (ph.2 data mid-year) as Bayer looks less competitive.” *Id.*

122. Jefferies also issued a report on April 1, 2020, addressing the recent abstracts released by Bayer and Shionogi as they relate to BELLUS, noting that:

Competitor BAY’s Ph1/2a data for BAY’080 (P2X3 inhibitor) appear not as strong vs. Shionogi’s S-600918. Combined with [Merck]’s gefapixant low dose Ph3 failure, this is positive for [BELLUS]. If [BELLUS]’s Ph2 successfully shows at least similar efficacy/safety as S-600918 (data in mid-2020), BLU-5937 would be positioned as a very competitive agent for chronic cough.⁴⁰

123. The report went on to add that “[i]f [BELLUS] is able to select the dose from Ph2, [] [BELLUS] could be ahead of both Bayer and Shionogi.”

5. Despite the Increasingly Public Data, BELLUS Failed to Adjust its Phase 2 Design or Disclose the Growing Risk of Failure as a Result of the Low Number of Severe Cough Enrollees

124. At the time of the IPO, unbeknownst to investors, the design of the RELIEF trial, setting a low cough frequency threshold of more than 10 coughs per hour, had failed to prevent the enrollment of a low number of severe cough patients or assist in the screening of low cough frequency patients. As a result, BELLUS was at a high risk of failing to meet the designated

⁴⁰ Jefferies LLC, *BELLUS: Competitor BAY’s Ph2 Data Do Not Move Bar for BLU; Investor Event in ~End-May*, (Apr. 1, 2020).

primary endpoint for efficacy for its Phase 2 trial, of having to spend the time and money to conduct another Phase 2 trial, falling further behind the leader of the pack of drugs vying to be the first FDA approved therapy for suppressing chronic cough – Merck’s P2X3 antagonist, gefapixant – and reducing the likelihood that the Company would reap the financial rewards of being the first P2X3 antagonist to market with little to no side effects. Since Merck, and two other competing developers of P2X3 antagonists, Bayer and Shionogi, had already successfully completed their Phase 2 clinical studies, investors were expecting BELLUS to be able to adequately design the RELIEF trial to account for the correlation between high cough frequency and efficacy.

125. Indeed, the Company specifically distinguished itself from competitors by touting the experience of its management, which included the Individual Defendants and Defendant Smith. For example, the Company’s Jefferies and Cowen Presentations pointed to its “Experienced Team” of “Management with track record of execution” which included Defendants Bellini and Desjardins⁴¹:

BELLUS Overview

Lead Program: BLU-5937

Highly Selective P2X3 Antagonist for Chronic Cough:

- Large population with significant unmet need
 - Indication of interest by big pharma (e.g. Merck and Bayer)
 - Phase 1 suggests best-in-class potential
 - Clinically validated target reduces clinical risk
 - Phase 2 underway with data expected in mid 2020
-

Pipeline within a Molecule

2nd indication in chronic pruritus associated with atopic dermatitis with potential for broad applicability in hypersensitization disorders

Cash Runway Beyond Proof-of-Concept

~\$100M (C\$132M)¹ cash position

Robust IP

Patent estate including composition of matter covering BLU-5937 and related compounds expiring in 2034

Experienced Team

Management with track record of execution

⁴¹ Presentation of Bellus Health, *Jefferies London Healthcare Conference Corporate Presentation*, (Nov. 20, 2019), <https://www.jeffries.com/CMSFiles/Jeffries.com/files/BELLUS%20Health%20Inc.pdf>.

126. During Class Period calls with investors, Defendant Bellini similarly boasted about the experience and expertise of the Company's management and Board:

- “[T]he core part of the senior management team has worked together for a long time. This is our second project together. And then more recently, in August of last year, Cathy Bonuccelli joined us. Cathy spent the last 25 years at GSK and Astra doing late-stage drug development in the respiratory space specifically, which obviously is ***the right kind of expertise that we want in our current project.***”⁴²
- “[W]e think that we've put together a great team to execute on this project. I've talked a little bit about the management team, about Cathy Bonuccelli recently joining us. We think ***we have a deeply experienced Board of Directors supporting us at the clinical advisory board level.*** I think it's important to note the inclusion of Dr. Jacky Smith, Dr. Smith runs the largest cough clinic in the world out of the University of Manchester in the U.K. She's been involved in almost all of the chronic cough trials, including the ones from Merck. She's currently the principal investigator in our Phase II trial as well.” *Id.* at 6.“We're very happy to have ***Professor Jacky Smith,*** join us to speak. She's a ***world-renowned expert in chronic cough,*** based in Manchester in the U.K. where she oversees a large cough clinic associated with the University of Manchester. She has been involved in many of the chronic cough trials and is the principal investigator for our Phase II trial.”⁴³

127. As early as March 25, 2019, LifeSci Capital had issued an analyst report detailing conversations with leading chronic cough experts regarding the P2X3 antagonist class, specifically about the need to design trials to account for the correlation between higher cough severity and efficacy.⁴⁴ Notably, a clinical pulmonologist—who, at the time, ran one of the largest cough centers in the U.S. and was involved with many of the cough programs in development—believed that: “P2X3 antagonists will also be clinically effective in acute cough and thinks that Merck’s recent Phase II failure [(Merck had recently terminated a clinical study of gefapixant in acute

⁴² Transcript of BELLUS Health Inc. Annual Shareholders Meeting, THOMSON REUTERS at p.5 (May 14, 2020, 06:30 PM GMT).

⁴³ Transcript of BELLUS Health Inc. Corporate Call, THOMSON REUTERS at p. 2, (May 27, 2020, 1:00 PM GMT).

⁴⁴ LifeSci Capital LLC, Alpha Series, *Bellus Health: Insights from Additional Chronic Experts Continue to Support the Selective P2X3 Antagonist Approach* (Mar. 25, 2019).

cough patients with induced upper respiratory tract infection)]⁴⁵ could be due to trial design rather than the drug class. The expert mentioned that healthy individuals infected with virus may not cough enough to elicit a statistical response, and there is a wide range of cough severity between patients. Ultimately, a better trial design could improve results.”

128. Even as more clinical data, solidifying the correlation between efficacy and cough frequency, became public, BELLUS continued to fail to implement revised or new trial protocols to increase the number of severe cough patients enrolled, subjecting the Company to an increasing risk of failing its Phase 2 endpoints.

129. On December 12, 2019, while BELLUS was still in the process of enrolling patients for the RELIEF trial, LifeSci Capital issued a report on recent interactions with one of the top cough experts and Bellus Health management team.⁴⁶ That report acknowledged that a key takeaway from the interactions was “[t]he virus model that Merck used in its acute cough study result[ed] in a wide range of cough frequency, and its study termination might be due to patients not coughing enough at baseline.”

130. Based on all the available clinical data, the 1934 Act Defendants knew or should have known that, in order for BLU-5937 to meet its Phase 2 endpoint and ultimately become a commercial success, it would have to show that the drug was as effective as competitor P2X3 antagonists. Yet the 1934 Act Defendants knew and disregarded the clinical data demonstrating the direct correlation between cough frequency and efficacy.

⁴⁵ ClinicalTrials.gov, Study of Gefapixant (MK-7264) in Acute Cough for Participants With Induced Viral Upper Respiratory Tract Infection (URTI) (MK-7264-013) (June 26, 2018 last updated Dec. 10, 2019), <https://clinicaltrials.gov/ct2/show/NCT03569033?term=MK-7264&draw=2&rank=3> (last visited Sept. 17, 2021).

⁴⁶ LifeSci Capital LLC, Alpha Series, *Bellus Health: Additional Tidbits on the Chronic Cough Space Following Expert Dinner and Meeting with Management* (Dec. 12, 2019).

131. During the Class Period, BELLUS did not disclose to investors that it was struggling to find quality patients to enroll in its Phase 2 trial, imperiling its ability to meet the trial’s endpoint. In fact, while BELLUS was actively enrolling patients for the Phase 2 trial, the Company had held a KOL day during which it touted that Bluestar Bioadvisors (a third-party consulting group) had reviewed and confirmed its market analysis, which estimated that there were 2.6M primary addressable chronic cough patients that have been diagnosed for more than 1 year (inclusion criteria in clinical trials).⁴⁷

132. BELLUS reiterated this message during an industry conference held in January 2020. As a result, an analyst from Guggenheim Securities noted as a key conference takeaway, “BELLUS’ Phase 2 RCC recruitment and top line data remain on track for mid-year.”⁴⁸

133. Even when, on May 27, 2020, during a KOL event hosted by the Company, BELLUS noted that ~50% of patients in Phase 2 were previously enrolled in competitors’ trials, it did not raise any issues about the enrollment.⁴⁹ The only concern addressed by the Company was the potential of patients noticing taste AEs more easily, but a chronic cough expert added that the Company’s crossover design of Phase 2 should mitigate such effects.

VI. THE 1934 ACT CLAIMS

134. Plaintiff asserts securities fraud-based claims under §§ 10(b) and 20(a) of the 1934 Act and SEC Rule 10b-5, promulgated thereunder, against BELLUS, Defendant Smith, the Individual Defendants, and the Underwriter Defendants (the “1934 Act Defendants”).

⁴⁷ LifeSci Capital LLC, Alpha Series, *Bellus Health: ERS Abstract from P2X3 Competitor Shionogi Results Continue to Support a Selective P2X3 Approach, Although Taste Effect with S-600918 is Less than Expected* (Sept. 22, 2019).

⁴⁸ Guggenheim Securities, LLC, *Key Takeaways from Meetings Last Week: BLU, EBS, ENDP, EYPT, HZNP, TXMD* (January 21, 2020).

⁴⁹ Jefferies LLC, *BELLUS: Virtual KOL Event on Chronic Cough; Ph2 Data Reiterated for June/July* (May 27, 2020).

135. Throughout the Class Period, the 1934 Act Defendants knowingly or recklessly made materially false and misleading public statements and omissions that: (i) BELLUS was struggling to enroll quality patients in its Phase 2 trial for BLU-5937; (ii) the low cough frequency threshold of 10 coughs per hour that BELLUS set for its Phase 2 trial resulted in a low number of severe cough patients being enrolled; (iii) as a result, BELLUS’s Phase 2 trial had failed to adequately account for the correlation between higher cough frequency and higher efficacy that Merck’s studies had already demonstrated; (iv) the design flaw in BELLUS’s Phase 2 trial meant there was at high risk it would not meet its designated primary endpoint for efficacy, which would cause the Company to fail the Phase 2 trial, to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales; and (v) as a result of the foregoing, Defendants’ positive statements about the Company’s business, operations and prospects, were materially misleading and/or lacked a reasonable basis.

A. Defendants’ Materially False and Misleading Statements and Omissions During the Class Period⁵⁰

136. On September 3, 2019, BELLUS filed with the SEC, a Form-10 Registration Statement consisting of a preliminary prospectus supplement to its short form base shelf prospectus dated July 26, 2019, in accordance with the MDS (the “Registration Statement”). The Individual Defendants signed and/or authorized the signing of the Registration Statement.

137. On September 5, 2019, BELLUS filed with the SEC its final amendment to the Registration Statement, constituting the Prospectus for the IPO (together with the Registration Statement, the “IPO Documents”). The IPO Documents, listed on the first page, Defendants Jefferies, Cowen, Baird, Guggenheim Securities and Bloom Burton Securities, as the underwriters

⁵⁰ The particular portions of the statements alleged to be false or misleading are in bold and italics in this section.

, with Defendants Jefferies, Guggenheim Securities and Bloom Burton Securities as “joint book-running managers”, Defendant Cowen acting as lead manager, and Defendant Baird acting as co-manager. The IPO Documents remained alive and uncorrected throughout the Class Period.

138. The IPO Documents contained materially false and/or misleading statements about BELLUS’s BLU-5937 and how it compared to Merck’s gefapixant, stating in relevant part:

We believe that doses of 50 mg to 100 mg administered twice-daily (BID) would result in the desired level of therapeutic activity. *In contrast, gefapixant, a product candidate in development by Merck & Co., was reported to cause taste alteration and/or taste loss in up to 80% of patients at the therapeutically relevant dose of 50 mg BID in a Phase 2 clinical trial.*

In July 2019, we enrolled our first patient in our ongoing Phase 2 clinical trial for BLU-5937 for the treatment of refractory chronic cough, with topline data expected in mid-2020.

139. The IPO Documents specifically provided information about the clinical development of gefapixant as support for the expected efficacy BLU-5937:

The only clinically validated treatments in development for refractory chronic cough are molecules that inhibit the P2X3 receptor. Merck & Co.’s gefapixant, a low selectivity P2X3 inhibitor, is the most advanced in clinical development and is currently undergoing clinical evaluation in two Phase 3 trials. Gefapixant is a non-narcotic, low selectivity P2X3 inhibitor which has been shown to alleviate refractory chronic cough symptoms and improve patients’ quality of life in Phase 2 clinical studies. Gefapixant’s potent antitussive effect comes coupled with a significant tolerability issue in the form of taste alteration and partial or complete taste loss for a significant proportion of patients.

Results from an initial Phase 2, double-blind clinical trial in patients with refractory chronic cough showed that treatment with a high dose of gefapixant (600 mg BID) led to a significant reduction in mean daytime cough frequency compared with placebo. A subsequent dose-escalation trial confirmed the clinical activity of gefapixant in refractory chronic cough patients even when testing a much lower dose (50 mg BID). Across all Phase 2 trials, dose-dependent taste alteration and taste loss was the most commonly reported adverse event. In a Phase 2b trial in which 50 mg gefapixant was given twice daily, 81% of patients reported taste side effects, 48% of patients reported taste alteration, 24% had partial loss of taste and 21% had complete taste loss.

* * *

We are developing BLU-5937, a potent, highly selective, orally bioavailable small molecule inhibitor of the P2X3 receptor, as an oral therapy to reduce cough frequency in chronic cough patients. *Advances in the understanding of possible mechanisms underlying chronic cough have paved the way for product candidates targeting the P2X3 receptors, such as BLU-5937.*

140. The statements contained in ¶¶138-39 *supra* were materially false and misleading when made because the Individual Defendants and the Underwriter Defendants failed to disclose that despite Merck’s successful Phase 2 trial for gefapixant, which had “paved the way” for BLU-5937, the Company disregarded, in designing its Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though P2X3 antagonists were a “clinically validated treatment” for refractory chronic cough), which would cause it to fail the Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

141. In addition, while the Individual Defendants and the Underwriter Defendants list numerous “Risk Factors” in the IPO Documents, they failed to adequately warn investors that certain “Risk Factors” had already materialized at the time of the IPO. For example, the IPO Documents warned, in relevant part:

Competition in the biopharmaceutical industry is intense, and development by other companies could render BELLUS Health’s drugs or technologies non-competitive.

* * *

There are multiple companies developing products at varying stages of development specifically intended to treat chronic cough including Merck & Co., Bayer AG, Shionogi Inc., Attenua Inc. and NeRRe Therapeutics Ltd, some of which have substantially greater product development capabilities and financial,

scientific, marketing, and human resources than us. Of these companies, Merck, Bayer and Shionogi are developing P2X3 antagonists for chronic cough that *could compete* directly with BLU-5937.

142. The generic statements of “intense” competition and that other companies’ drug development “could render” BELLUS’s drug product(s) “non-competitive” and other P2X3 antagonists “could compete” with BLU-5937, contained in ¶141 *supra*, were materially false and misleading when made because the Individual Defendants and the Underwriter Defendants failed to disclose that the Company was falling behind its competitors not because of its competitor’s development or pace of it, but because of its own poor design of its Phase 2 trial. BELLUS had disregarded the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated and set a low cough frequency threshold of 10 coughs per hour to enroll patients in the Company’s Phase 2 trial, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail the Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

143. On November 14, 2019, BELLUS issued a press release reporting its financial and operating results for the third quarter ended September 30, 2019 (“3Q19 Press Release”). The 3Q19 Press release stated, in relevant part, that:

First Patient Enrolled in the Ongoing Phase 2 RELIEF Trial of BLU-5937 for the Treatment of Refractory Chronic Cough: In July 2019, the Company enrolled the first patient in the Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough. *The trial is evaluating the efficacy and safety of BLU-5937 and is expected to build on the Phase 1 evidence showing little to no impact on taste.*

144. The 3Q19 Press Release further stated, in relevant part, that:

BELLUS Health is currently conducting a Phase 2 clinical trial of BLU-5937 for patients with refractory chronic cough, which is referred to as the RELIEF (A Randomized, Double-blind, Placebo-Controlled, Crossover, Dose Escalation Trial of BLU-5937 in Subjects with Unexplained or Refractory Chronic Cough) trial. The trial was initiated in July 2019 and the Company expects to report topline data in mid-2020.

The RELIEF trial is a randomized, double-blind, placebo-controlled, dose escalation and two-period crossover design trial to assess the efficacy, safety and tolerability of BLU-5937 at four doses: 25, 50, 100 and 200 mg BID. Doses are escalated at four-day intervals. **Approximately 65 patients with refractory chronic cough are expected to be enrolled** at approximately 15 clinical sites located in the United Kingdom and United States. BELLUS Health enrolled the first patient in the RELIEF trial at the end of July 2019 and is actively recruiting patients.

145. The statements contained in ¶¶143-44 *supra* were materially false and misleading when made because the Individual Defendants failed to disclose that BELLUS had disregarded, in designing the RELIEF trial, the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated. Specifically, the RELIEF trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which resulted had in a low number of severe cough patients being enrolled. This design flaw in the RELIEF trial meant there was a high risk it would not meet its designated primary endpoint for efficacy, which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

146. On November 20, 2019, Defendant Bellini presented at the Jefferies London Healthcare Conference on behalf of the Company.⁵¹ The slides for that presentation included one which stated, in relevant part, that the “Lead Program: BLU-5937” was a “Highly Selective P2X3 Antagonist for Chronic Cough” whose “**Clinically validated target reduces clinical risk**”.

⁵¹ BELLUS Health Inc., *BELLUS Health to Present at Jefferies Global Healthcare Conference in London* (Nov. 13, 2019), <https://ir.bellushealth.com/node/8651/pdf>.

147. The Jefferies Presentation later stated, in relevant part, that “*P2X3 is a clinically validated target, with multiple positive Phase 2 trials*, with low and high selectivity P2X3 antagonists” while also depicting results from Merck and Shionogi’s Phase 2 trials in a slide titled “Clinical Data Further Validates P2X3 Target”.

148. The statements contained in ¶¶146-47 *supra* were materially false and misleading when made because while P2X3 was “a clinically validated target, with multiple positive Phase 2 trials”, Defendant Bellini failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

149. On February 27, 2020, BELLUS issued a press release reporting its full year 2019 (“FY19”) financial results and business highlights on BLU-5937 (2.27.20 Press Release) which quoted Defendant Bellini as stating that “[l]ast year was highlighted by the initiation of our Phase 2 RELIEF trial of BLU-5937 in chronic cough, as well as by our US\$79.4 million equity offering and beginning of trading on the Nasdaq exchange. *These critical achievements have positioned BELLUS Health to execute on this year’s upcoming milestones and development plans, including the data readout for the RELIEF trial in chronic cough...”*

150. The 2.27.20 Press Release went on to state, in relevant part, “*[i]n July 2019, the Company enrolled the first patient in the Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough. The Company expects to complete patient enrollment by the end of March*, with topline results anticipated in mid-2020.”

151. The 2.27.20 Press Release further states:

The P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it *has been validated in multiple clinical trials with different P2X3 antagonists*. ... The Company believes that its highly selective P2X3 antagonist can also reduce coughing in patients with chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors. *This hypothesis has been validated in a recent clinical trial with a more selective antagonist of P2X3*; however, BLU-5937 is the most selective of the P2X3 antagonists currently being studied.

152. The statements contained in ¶¶149-51 *supra* were materially false and misleading when made because while other P2X3 antagonists have been “validated in multiple clinical trials”, the Individual Defendants failed to disclose that BELLUS had disregarded, in designing its RELIEF trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the RELIEF trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in the RELIEF trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause BELLUS to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

153. On March 3, 2020, Defendant Bellini presented at the Cowen 40th Annual Health Care Conference on behalf of the Company.⁵² The slides for the presentation included one which stated, in relevant part, that the “Lead Program: BLU-5937” was a “Highly Selective P2X3 Antagonist for Chronic Cough” whose “***Clinically validated target reduces clinical risk***”.⁵³

154. Another slide in the Cowen Presentation titled “***BLU-5937 Selectivity Resulted in Differentiated Taste Profile***” stated, in relevant part, that “[a]t estimated therapeutic doses and based on clinical trial results to date: BLU-5937 has significantly improved taste effect profile versus MK-7264”. The very next slide was titled “Preclinical Data Validates P2X3 for Cough”, which noted in relevant part that “***Preclinical data supports BLU-5937 having comparable efficacy to MK-7264***”. Then, the next slide, titled “Clinical Data Further Validates P2X3 Target”, noted in relevant part that “***P2X3 is a clinically validated target, with multiple positive Phase 2 trials***, with low and high selectivity P2X3 antagonists” and depicted results from Merck and Shionogi’s Phase 2 trials.

155. The statements contained in ¶¶153-54 *supra* were materially false and misleading when made because while P2X3 was “a clinically validated target, with multiple positive Phase 2 trials”, Defendant Bellini failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it

⁵² BELLUS Health Inc., *BELLUS Health to Present at Two Upcoming Healthcare Investor Conferences* (Feb. 20, 2020), <https://ir.bellushealth.com/node/8761/pdf>.

⁵³ Presentation of BELLUS Health, Cowen 40th Annual Health Care Conference (Mar. 3, 2020), <https://ir.bellushealth.com/static-files/c332483c-a1e2-45e3-805e-d33c4c95a7c5>.

would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

156. On March 19, 2020, BELLUS announced “that it has completed patient enrollment for the RELIEF trial, its dose-escalation, placebo-controlled Phase 2 trial of BLU-5937 in patients with refractory chronic cough” (3.19.20 Press Release).⁵⁴ In the 3.19.20 Press Release, Defendant Bellini is quoted as noting that “[c]ompleting patient enrollment for the RELIEF trial is an important achievement in the BLU-5937 development program,” “BLU-5937 has the potential to address a significant unmet medical need in chronic cough, and we believe our compound may be better tolerated than competitor candidates due to its high selectivity, potentially reducing cough frequency with little to no taste alteration.”

157. The statement contained in ¶156 *supra* was materially false and misleading when made because while touting the completion of “patient enrollment for the RELIEF trial”, the Individual Defendants failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and

⁵⁴ *BELLUS Health Announces Completion of Enrollment in Phase 2 RELIEF Trial of BLU-5937 for the Treatment of Refractory Chronic Cough*, BUSINESS WIRE (Mar. 19, 2020 07:00 AM ET), <https://www.businesswire.com/news/home/20200319005092/en/BELLUS-Health-Announces-Completion-Enrollment-Phase-2>.

Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck in the race towards FDA approval and drug sales.

158. On April 6, 2020, the Company announced the completion of “patient dosing in its Phase 2 RELIEF clinical trial of BLU-5937 for the treatment of refractory chronic cough,” explaining that “[w]ith 52 patients having completed dosing, ***the RELIEF trial is powered at more than 80% to see a 30% difference between BLU-5937 and placebo in awake cough frequency***” (4.6.20 Press Release).⁵⁵

159. In the 4.6.20 Press Release, Defendant Bellini is quoted as stating that “[w]ith 52 patients completing dosing, the RELIEF trial is the largest crossover study conducted in refractory chronic cough, ***providing the powering needed to evaluate efficacy and safety of BLU-5937,***” and “[g]iven the ***robust number of patients*** and the impact of the Covid-19 pandemic, we concluded that it was prudent to close the trial [early] as our primary focus is the safety and well-being of our trial participants, clinical investigators and their site staffs.”

160. The statements contained in ¶¶158-59 *supra* were materially false and misleading when made because while touting the “robust number of patients” which provided sufficient “power” and in the RELIEF trial, the Individual Defendants failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2

⁵⁵ BELLUS Health Inc., *BELLUS Health Announces Completion of Dosing in Phase 2 RELIEF Trial with BLU-5937 for the Treatment of Refractory Chronic Cough*, (Apr. 6, 2020), <https://ir.bellushealth.com/node/8886/pdf>.

trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

161. On May 12, 2020, Defendant Bellini presented at the Bank of America Merrill Lynch Healthcare Conference on behalf of the Company (“BofA Conference”).⁵⁶ He specifically states, in relevant part, that:

So the lead product here probably that's the most advanced is **MK-7264** and P2X3 antagonist that's currently in Phase III trials from Merck. That drug **works really, really well in this patient population. Shows significant decrease in cough**, but at the same time has a liability, a tolerability issue with about 80% of patients having some form of taste effects, so either taste alteration or taste loss.

We think we've solved that problem by having a highly selective P2X3 antagonist. Definitely based on our Phase I data generated to date, we see a very low percentage of patients having taste effect. And **we're now in our Phase II trial in chronic cough patients** and should have a data readout on that midyear this year.

162. Later during the BofA Conference, Defendant Bellini further states that:

[O]bviously it makes a lot of sense to develop small molecules to inhibit this [P2X3] receptor to treat these refractory chronic cough patients. And if we go on Slide 10, I think it's obviously easy for me to tell you that, that mechanism is a rational one because **we know that it works at this point**. So on this slide, **I'm showing you data from a Merck Phase II B study where they treated patients over a 12-week period**. This is the data from the 50-milligram dose. So **they've shown 57% reduction in cough frequency from baseline, 37% placebo adjusted. This is the kind of level of efficacy that you see from MK-7264 across all their trials**. It's like 50% to 60% reduction from baseline in cough, so consistently shows benefit in these patients. This is considered a significant improvement for these patients. Kind of like minimal clinical improvement is more around the 30% nominal reduction. So obviously at the 50%-plus range, it is an important improvement.

This is considered a breakthrough therapy. The original data was published in The Lancet. And when you speak to investigators and to patients, I think **everyone really appreciates it for the efficacy**.

* * *

⁵⁶ Transcript of BELLUS Health Inc. at Bank of America Merrill Lynch Healthcare Conference (Virtual), THOMSON REUTERS (May 12, 2020, 5:00 PM GMT).

The Merck product is only slightly selective, so only slightly more potent at the homotrimer versus the heterotrimer, which means that ***at their effective dose of 50 milligrams, it is having the effect on the cough.***

* * *

I was really thinking about ***can we generate the same level of efficacy to the Merck product.*** I think ***we've answered that question in the animal.*** So maybe quickly on Slide 15 when you look at expression analysis in the upper airway of the guinea pig. It's almost exclusive P2X3 hence formation of the homotrimer, P2 -- the P2X3 homotrimer. That translates into really nicely when you look at the gold standard guinea pig cough model. So this is a model where you trigger cough using citric acid and histamine. We're giving head-to-head increasing doses of 5937 and MK-7264. And as you can see here on Slide 15, ***exact same efficacy between the 2 compounds, even though 5937 is much more selective than the Merck compound.***

If we go on to Slide 16, what about in the human? So here, we don't have our own human efficacy data yet. That's really what we're going to read out midyear this year, but we do have some data from some of our competitors. So ***our 2 other competitors that are developing more selective antagonists are Shionogi and Bayer. They've both reported on their Phase II trials.*** Shionogi's selectivity is about 250-fold. Bayer's selectivity has not been disclosed. We estimate that, based on their IP filings, to be somewhere between 25- and 125-fold. But just to give you a sense that ***these 2 are more selective than the Merck compound,*** and as you can see here when you look across in terms of efficacy, ***Shionogi*** was only tested at one dose, 150 mgs QD. It ***is quite comparable to the Merck product in terms of efficacy.*** Bayer has come in a little bit lighter at 25% placebo-adjusted. They have not disclosed the nominal rate. But overall in discussions with investigators that have used these products, ***both Shionogi and Bayer are clinically meaningful in terms of their efficacy. They've hit statistical significance in their Phase II trials. And so these next-gen agents definitely provide meaningful efficacy to patients.***

* * *

All 3 of the programs, Bayer, Shionogi and BELLUS are at relatively comparable stages of development in Phase II.

* * *

We have 2 Phase II trials that have been completed.

* * *

The study is currently completed. So we've recruited 68 patients. Unfortunately, we had 13 that were discontinued due to COVID and due to the situation around COVID. Nevertheless, ***we have 52 patients that completed all of the dosing and matching placebos.*** This is the largest, with the 52 patients, is the largest of the Phase II crossover trials. The other trials run, the Merck and Afferent trials were 30 patients, the Shionogi trial was 31 patients, and the recent Bayer trial was 40 patients. ***So we do feel very comfortable around the power of the trial, considering it's the largest that's been completed with this design.*** It's important to note ***all of those other trials readout with positive top line data.***

163. The statements contained in ¶¶161-62 *supra* were materially false and misleading when made because by touting the efficacy shown in the P2X3 Phase 2 trials by Merck, Shionogi and Bayer alongside BELLUS's "completed" P2X3 Phase 2 trial as "the largest", Defendant Bellini implied that the Company would have similarly "positive top line data." He further failed to disclose that the Company disregarded, in designing its Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated. Specifically, the Company's Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS's Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

164. On May 14, 2020, the Company held its annual shareholders meeting ("Shareholder Meeting").⁵⁷ During the meeting, Defendant Bellini stated in relevant part:

So on Slide 12, I'm showing you the data from MK-7264. This is a trial that was done over a 12-week period. But ***very consistently across numerous Phase II trials. Merck has shown very substantial reductions in cough frequency. So in this study, it was 57% from baseline. Placebo-adjusted was 37%. In previous Phase II trials definitely see a consistent kind of like 50% to 60% reduction*** in these patients. So very important and ***clinically meaningful effect for these patients.*** This is considered a breakthrough therapy for refractory chronic cough patients, and that's whether you speak to patients. Investigators results were published in The Lancet. So very good.

I think that there is -- so ***there's no real issue on the efficacy side.***

* * *

[I]t is wrapping up 2 Phase III trials currently. But ***the primary efficacy end point and the top line -- qualitative top line data has been released by Merck, and they***

⁵⁷ Transcript of BELLUS Health Inc. Annual Shareholders Meeting, THOMSON REUTERS (May 14, 2020, 6:30 PM GMT).

have said that the trial is successful at the top dose in terms of efficacy, and then that the safety and tolerability profile is in line with previous trials.

* * *

Here, I'm showing you animal data on 17. So the preclinical data that supports that. On the left-hand side is expression analysis. Looking at the expression of P2X2 and P2X3 in the upper airway, as you can see, it's almost exclusive expression of P2X3. So hence, the formation of the P2X3 receptor being the form that's driving the cough -- or the cough reflex in the airway. And that translates really nicely in the guinea pig cough model. In this case, we've gone head-to-head versus the Merck product at increasing doses. And as you can see, *whether you gave 5937 or 7264, even though the BELLUS product is much more selective, in this model, there's very similar levels of efficacy between the 2 compounds.*

Nice to have animal data, but I think it's just as important to look at clinical data to support that. The -- on Slide 18. So we don't have our own clinical data yet. We will have that in a couple of months from now. But *there's definitely data from our competitors that support that more selective agents can drive efficacy in this patient population.* So Shionogi's compound, as they reported, is 250-fold in terms of selectivity. So not quite at our 1,500-fold level but still quite selective. And in the case of Bayer, the selectivity, based on our estimate -- they have not disclosed this, but based on their IP, we believe that their selectivity is somewhere in the 25- to 125-fold range.

As you can see here, *both of those compounds generate statistically significant differences versus placebo. These are clinically meaningful differences as well.* So from our understanding, *patients that have taken these products appreciate the difference.* So definitely, *there is clinical validation that the more selective agents can drive an antitussive effect.*

* * *

And *our own Phase II data will be available coming up in June, July, so just in a couple of months.* I think order of entry is also important or state of development is important. And *it's important to note that all 3 of the -- of Bayer, Shionogi and BELLUS are at relatively similar stages of development, all in Phase II currently.*

* * *

On Slide 26 is the design of the Phase II trial. So this is a crossover design trial with 2 periods with a forced dose escalation. So every single patient takes all 4 doses, and they do that in 4-day incremental period. So someone comes into the study, they're randomized to placebo or drug. They do a baseline cough count and then they do 4 days at 25 milligrams, 4 days at 50, 4 days at 100, 4 days at 200. And at the end of each of those many periods, they have a cough count as well. They're washed out. And then they crossed over. So they cross over and they do matching either placebo or drug, period. So every patient takes -- has a cough count at all the doses and matching placebo, which is very strong from a stat perspective in generating power in this study.

To be clear, this isn't a study that we invented. This is a trial design that's been conducted many, many times. In the chronic cough space, it works very, very well. One thing of note here is that we did complete the study with 68 patients enrolled. Unfortunately, not all of those were able to complete the study due to the COVID environment. 52 patients did complete dosing. And even ***at 52 patients, this is the largest of the crossover design trials in the phase for Phase II in the refractory chronic cough space.*** So comparative studies that were completed by Afferent and Merck, where they did 3 studies with about 30 patients each. The Shionogi study that was completed was 31 patients, and the more recent Bayer trial was at 40 patients. So ***we do feel very comfortable around the powering due to the fact that we have 52 patients having completed all of the treatment periods.***

165. The statements contained in ¶¶164 *supra* were materially false and misleading when made because by touting the efficacy shown in the P2X3 Phase 2 trials by Merck, Shionogi and Bayer alongside BELLUS’s “completed” P2X3 Phase 2 trial as “the largest”, Defendant Bellini implied that the Company would have similarly “clinically meaningful” and “statistically significant differences versus placebo” in its Phase 2 trial. He further failed to disclose that the Company disregarded, in designing its Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

166. On May 27, 2020, the Company convened “a virtual Key Opinion Leader (‘KOL’) meeting to discuss the chronic cough landscape” (“KOL Meeting”).⁵⁸ During the KOL meeting,

⁵⁸ BELLUS Health Inc., *BELLUS Health Convenes Virtual KOL Meeting to Discuss the State of Chronic Cough Treatment and the BLU-5937 Program* (May 13, 2020), <https://ir.bellushealth.com/node/9501/pdf>.

Defendant Smith stated in relevant part:⁵⁹

P2X3 receptor antagonists are a clinically validated target based on the work that has been done by Merck with their drug gefapixant, known as MK-7264 on this trial. And this shows some results from a recently published study, one of a series of studies, where they looked at a range of doses from 7.5 to 50 milligrams of gefapixant over a 12-week parallel group study.

And as you can see from the plot in the middle and on the right-hand side here, at a dose of 50 milligrams, there was a statistically significant reduction in the number of times the patients coughed over the 12-week period at that dose. And this equated to a 37% reduction over and above the effect of placebo.

167. Later during the KOL Meeting, Defendant Smith stated, in relevant part:

So now I'm going to talk through the RELIEF study, which is a randomized, double-blind, placebo-controlled crossover study of BLU-5937 in patients with refractory or unexplained chronic cough. So **this trial is a Phase II, quite well tested study design now**. It is a crossover design, with the primary endpoint being a reduction in awake cough frequency, that I'll come to explain a bit further on the next slide. Altogether, 68 patients with refractory chronic cough have been recruited, 52 have completed dosing with 13 additional patients completing at least one of the treatment periods.

* * *

So **the primary endpoint in this study is objective for cough frequency**. And what I mean by that is the number of coughs that are captured with an acoustic recording device over a 24-hour period, both before and during treatment, with the various doses of study medication. This is captured with a digital recording device that I've been involved in the development of, which produces a report of the number of coughs using a semi-automated system, which removes the vast majority of speech and non-cough sounds, and allows the cough to be electronically tagged and their locations in time identified.

* * *

We're also selecting patients with more than 10 coughs per hour in order that we have a sufficient frequency of coughing so that we can delineate the effects of the different doses of drug. And alongside that, we're looking for patients who score more than 40 on a cough severity scale, so that we know that their cough is sufficiently frequent that it's causing them problems.

* * *

So how does this study compare to other similar Phase II studies of P2X3 antagonists performed by Merck and Shionogi? Well as you can see here, **it's very similar to many of the other Phase II trials that have been done, except the larger**

⁵⁹ Transcript of BELLUS Health Inc. Corporate Call, THOMSON REUTERS (May 27, 2020, 1:00 PM GMT).

numbers. Other Phase IIa trials have been very much in 20 to 30 patients, whereas this is a total of 68. The geographic region in terms of been doing in the U.K. -- done in the U.K. and U.S. is very similar, as is the baseline cough frequencies that we've seen in this study. And also ***the baseline cough severity scores, which, if anything, are at the higher end and more comparable to those seen in the Shionogi study.***

168. In response to a question from Defendant Bellini about the differences between the Company's trial patient population versus the general refractory patient population, Defendant Smith stated:

[I]ncluding the RELIEF study, more recently, studies have been also using a cough frequency cutoff. And so I think it's fair to assume the patients included in these studies are at the more severe end.

* * *

The cutoffs that we used are very much based around trying to select patients who have sufficient cough and sufficient severity in order to be able to demonstrate differences in a clinical trial.

169. The statements contained in ¶¶166-68 *supra* were materially false and misleading when made because while P2X3 was “a clinically validated target based on the work that has been done by Merck”, Defendant Smith failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck’s studies had demonstrated. Specifically, the Company’s Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled (even though Defendant Smith stated it was “fair to assume” otherwise). Thus, contrary to Defendant Smith’s assertions about how “well tested” and “similar” the Company’s Phase 2 trial was to its competitors, including “the baseline cough severity scores”, the design flaw in BELLUS’s Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and

money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

170. Also during the KOL Meeting, Defendant Bonucelli stated, in relevant part, that:

Dr. Smith has also shown you already that *the clinical data to date aligns well with this hypothesis, with the compounds that are more selective for the P2X3 homotrimers, maintaining efficacy for cough, but with substantially fewer taste side effects relative to the much less selective class leader, gefapixant.*

What then should we expect to see for BLU-5937, the P2X3 antagonist, with the highest known selectivity for P2X3 over P2X2/3? Let's look at efficacy first. Dr. Smith showed you this slide earlier in the presentation, illustrating that *all of the P2X3 antagonists studied to date, irrespective of selectivity, have resulted in clinically meaningful reductions in cough counts versus placebo, with placebo-adjusted reductions between roughly 25% and 35%.*

While comparisons across trials should be made with caution, it is noteworthy that *the reduction in cough, either from baseline or placebo-adjusted, is very similar for the most selective, that is the Shionogi compound, and the least selective, that is the Merck compound, studied to date, suggesting that the contribution of the P2X2/3 receptor in chronic cough is minimal. Although the Bayer compound with intermediate selectivity for P2X3 showed numerically lower reductions in cough than the Merck and Shionogi compounds, these improvements were, nonetheless, both highly statistically significant and clinically meaningful.* Therefore, for BLU-5937, confirming efficacy in the same range as was seen with these other members of the P2X3 antagonist class, in other words, between 25% and 35% reduction in cough versus placebo, will be a key measure of success from our RELIEF study.

* * *

Both Shionogi and Bayer, this year have started large traditional parallel arm Phase IIb studies with 3 active doses. Both of those studies will likely incur some delays to start-up and recruitment due to the COVID-19 pandemic. By our estimates, this would mean that they would start Phase III studies in 2022. Assuming that these projections are reasonable, ***BLU-5937 to be well positioned within the class from a timing perspective,*** based on our anticipated start of Phase III pivotal studies in 2021 or early 2022.

171. The statements contained in ¶170 *supra* were materially false and misleading when made because while “all of the P2X3 antagonists studied to date, irrespective of selectivity, have resulted in clinically meaningful reductions in cough counts versus placebo”, Defendant Bonucelli failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation

between high cough frequency and high efficacy that Merck's studies had demonstrated. Specifically, the Company's Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. Thus, contrary to Defendant Bonucelli's assertion that BLU-5937 was "well positioned within the class", the design flaw in BELLUS's Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

172. The slides for the KOL Meeting included one titled "***P2X3 Receptor: Clinically Validated Target***" which provided results from Merck's "MK-7264 Phase 2b Study (257 patients; 12 weeks)", including "reduction in awake cough frequency of **57% vs baseline and 37% vs placebo** at 50mg dose" ("KOL Presentation").

173. Another slide in the KOL Presentation focused on the selectivity of BLU-5937 versus Merck's MK-7264:

- **Selective P2X3 antagonists** would help grow adoption of P2X3 class and
 - [...] ... The 2nd generation drugs are more attractive than the Merck drug, so I think it would make me more likely to prescribe to even more of my refractory chronic cough patients ..." - *Primary Care Physician, United States*
- **Selective P2X3 antagonists** would be physicians' first option once available
 - "... These 2nd gen drugs have comparable efficacy than the Merck drug but much more favorable tolerability profiles. If these came to market and are reasonably priced, they would be my go-to option for my RCC patients ..." - *Pulmonologist, United States*

174. The statements contained in ¶¶172-73 *supra* were materially false and misleading when made because while P2X3 was "a clinically validated target", Defendants Smith and Bonucelli failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the

correlation between high cough frequency and high efficacy that Merck's studies had demonstrated. Specifically, the Company's Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS's Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail its Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

B. Additional Scienter Allegations

1. BELLUS, the Individual Defendants, and Defendant Smith

175. As alleged herein, BELLUS, the Individual Defendants, and Defendant Smith acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere and in furth detail herein, the Individual Defendants and Defendant Smith, by virtue of their receipt of information reflecting the true facts regarding BELLUS and its sole drug product, BLU-5937, their control over, and/or receipt and/or modification of BELLUS's allegedly materially misleading misstatements and/or their associations with the Company, which made them privy to confidential proprietary information concerning BELLUS, participated in the fraudulent scheme alleged herein.

176. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity of, or at least the reckless disregard by,

personnel at the highest levels of the Company, including the Individual Defendants and Defendant Smith. Given their executive level positions with BELLUS, the Individual Defendants and Defendant Smith controlled the contents of BELLUS's public statements during the Class Period. The Individual Defendants and Defendant Smith were each provided with or had access to the information alleged herein to be false and/or misleading prior to or shortly after its issuance and had the ability and opportunity to prevent its issuance or cause it to be corrected. Because of their positions and access to material non-public information, the Individual Defendants and Defendant Smith knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were false and misleading. As a result, each of the Individual Defendants and Defendant Smith were responsible for the accuracy of BELLUS's corporate statements and is, therefore, responsible and liable for the representations contained therein.

177. Plaintiff also alleges that scienter of the Individual Defendants and Defendant Smith (who, as executive officers and/or advisors of BELLUS, knew or recklessly ignored facts relating to its core operations) can be imputed to the Company.

178. Further evidencing their scienter, the Individual Defendants and Defendant Smith were intimately involved and acutely aware of the clinical development of P2X3 antagonists in general, and BLU-5937 in particular, for the treatment of refractory chronic cough, as indicated by their Class Period statements. For example, as a Jefferies analyst highlighted on February 28, 2020, “[BELLUS] is excited about the drug-drug interaction data showing only mild, transient taste alteration, occurring only on 1st day of dosing, in n=2/27 (7%) on 200mg BID for 10 days

(higher than the expected therapeutic dose of 50/100mg BID).⁶⁰

179. The Individual Defendants and Defendant Smith were also actually aware or had access to information about the Company’s Phase 2 trial, including the difficulties enrolling quality patients, the low cough frequency threshold for enrolling patients, the low cough frequency of patients being enrolled, the low number of severe cough patients being enrolled, and that BLU-5937 was not significantly improving patients’ coughs.

180. In addition to the alleged materially false and misleading statements referenced in §VII.A., the Individual Defendants and Defendant Smith spoke with knowledge about the Company’s Phase 2 trial during meetings with industry analysts who subsequently published reports based on the Individual Defendants’ and Defendant Smith’s statements at those meetings. For example, on November 26, 2019, Jefferies issued a report detailing its takeaway from a recent investor meeting it hosted with Defendants Bellini and Bonuccelli.⁶¹ Regarding the anticipated RELIEF data, Jefferies noted that BELLUS “conservatively expects to show comparable efficacy as competitors (Shionogi’s S-600918 & Merck’s gefapixant) with little/no taste-related AEs given its high selectivity.” The report went on to add that the Company “view[ed] ~40-60% reduction in cough frequency from baseline, not placebo-adjusted, as comparable to competitors (53%/57% reduction from baseline for S-600918/gefapixant in Ph2).”

181. Again, on March 17, 2020, during a call between analysts from Guggenheim Securities, LLC and BELLUS Management, including Defendant Bellini and Dr. Bonuccelli, following the release of Merck’s Phase 3 gefapixant data, the Company noted that their Phase 2

⁶⁰ Jefferies LLC, *BELLUS: In-line 4Q19 Net Loss; Major Inflection Point Within the Next ~6 Months* (Feb. 28, 2020).

⁶¹ Jefferies LLC, *Investor Meeting with BLU Management* (Nov. 26, 2019).

study remained on-track with data expected mid-year.⁶² Specifically, “[BELLUS] noted that more than 70% of their patients have already completed the trial (i.e. ~50 patients), putting the company in a good position (Shionogi’s phase 2a study was only in ~30 patients and borderline hit statistical significance).” Notably, “when asked if in the worst case COVID-19 were to severely impact the study (which is not expected), management estimated that with 50 patients there still would be roughly 80% power to detect a 35% difference.”

182. And as noted in an analyst report issued on April 16, 2020, Defendants Bellini and Bonuccelli acknowledged that the Company’s Phase 2 trial was nearly identical to Merck’s first Phase 2b trial—a 2-period crossover study, forced dose escalation with a washout in between.⁶³ Indeed, Defendants Bellini and Bonuccelli described BLU-5937 as most similar to gefapixant in terms of PK and rapid onset of effect, therefore, they believed 4 days of dosing should be enough. Defendants Bellini and Bonuccelli added their belief that “baseline cough frequency and patient exclusion (severe lung disease, smokers, etc.) should be similar across trials, where studies so far have shown that patients with higher cough frequency have had greater response.”

183. Following BELLUS’s virtual KOL event, led by Defendant Smith, with a chronic cough specialist to discuss unmet needs in chronic cough and potential path to initiation of Phase 3 trial, Jefferies, LLC reported a key takeaway from the event was the Company’s “baseline patient characteristics for Ph[ase] 2 are similar to competitors’ prior Ph2 trials: ***awake cough frequency/hour of 40.3***, average age of 64.2 y.o., & average duration of cough of 13.9 yrs.”⁶⁴

⁶² Guggenheim Securities, LLC, *BLU (Buy) – Takeaways From Our Follow-up Call with Management; BLU Ph.2 Study On Track for Mid-year* (Mar. 17, 2020).

⁶³ Guggenheim Securities, LLC, *BLU (Buy) – Takeaways From Our Fireside Chat with Management* (Apr. 16, 2020).

⁶⁴ Jefferies LLC, *BELLUS: Virtual KOL Event on Chronic Cough; Ph2 Data Reiterated for June/July* (May 27, 2020).

184. Given the Individual Defendants' and Defendant Smith's knowledge of what the high selectivity of BLU-5937 potentially meant not only for its side effects, but its efficacy, and their misleading statements about BLU-5937's competitive advantages made contemporaneously with that knowledge, Defendants' materially false and/or misleading statements alleged herein were made willfully and caused BELLUS common stock to trade at artificially inflated prices during the Class Period.

2. The Underwriter Defendants

185. It is well understood within the investment banking and financial communities that an underwriter's role (and duty) is to ensure that all material information is included in the offering documents and that no material information is omitted that is needed to make the information provided therein not misleading. Moreover, that underwriter has an express duty to perform a reasonable due diligence investigation of the company for which they are selling securities, and to verify the accuracy of disclosure concerning the company's securities offerings.

186. Further, the underwriter controls what information is in the prospectus, which incorporates the registration statement, and it controls the dissemination of that information to potential investors. Thus, an underwriter, such as the Underwriter Defendants named in this Action, has ultimate control over the contents and dissemination of the disclosure document, *i.e.* the IPO Documents. It must either make full disclosure or not underwrite the offering if full disclosure is not provided.

187. Any underwriter, such as the Underwriter Defendants named in this Action, must know that investors expect the investment banks, whose names appear on the IPO Documents, to perform a reasonable due diligence investigation of the issuing entity to ensure, to the best of their ability, that the IPO Documents do not include any false or misleading statements of material information, nor omits any material information. The investment banks, by putting their names on

the IPO Documents, are communicating to investors that they have in fact undertaken a reasonable due diligence investigation and are making full disclosure of all material information in the IPO Documents. Indeed, without having performed a reasonable due diligence investigation of the issuer, it would not be possible to make full disclosure.

188. If an investment bank, based on its due diligence investigation of the issuer, believes that any of the information in the IPO Documents is false or misleading, or omits material information, it has the authority and affirmative obligation to change the information, or if others refuse to change the information, then it should not underwrite the offering. But, if the investment bank allows its name (or names) to appear on the cover of the IPO Documents, then it is communicating to potential investors that it is satisfied, based on its reasonable due diligence investigation, that the IPO Documents are accurate and not misleading.

189. The Underwriter Defendants that underwrote the Company's IPO had control over the contents and dissemination of the IPO Documents. Their names are prominently featured on the cover of the IPO Documents. The co-managing underwriters actively participated in creating the IPO Documents, and investors expected that the Underwriter Defendants ensured that the IPO Documents provided appropriate disclosure of all material information.

190. The Underwriter Defendants had a duty to independently conduct a due diligence investigation of BELLUS for the IPO. Each Underwriter Defendant claims to have special expertise relevant to the underwriting of the Company's IPO and investors reasonably relied upon such expertise to ensure that a thorough due diligence investigation of BELLUS was conducted and full disclosure of all material information was made in the IPO Documents.

191. Specifically, as described in Section III.B.4. above, the information the Underwriter Defendants provide to the public emphasized their purported high standards and generally assures investors about the quality of their work.

192. As alleged herein, the Underwriter Defendants acted with scienter in that they either knew or recklessly disregarded the fact that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading, that such statements or documents would be issued or disseminated to the investing public, and the Underwriter Defendants substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere and in detail herein, the Underwriter Defendants, by virtue of their receipt of information reflecting the true facts regarding BELLUS and its sole drug product, BLU-5937, their control over, and/or receipt and/or modification of BELLUS's allegedly materially misleading misstatements and/or their associations with the Company, which made them privy to confidential proprietary information concerning BELLUS, participated in the fraudulent scheme alleged herein.

C. Loss Causation

193. The two declines in BELLUS's share price during the Class Period as alleged herein are actionable. The timing and magnitude of the Company's share price declines on each of those days negates any inference that the losses suffered by Plaintiff and the Class was caused by changed market conditions, macroeconomic or industry factors or BELLUS-specific facts unrelated to BELLUS, the Individual Defendants, Defendant Smith and the Underwriter Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members was a direct result of the 1934 Act Defendants' fraudulent statements and the corresponding artificial inflation in BELLUS's securities prices and the subsequent significant

decline in the value of BELLUS's securities when the 1934 Act Defendants' prior acts of misconduct were revealed.

194. At all relevant times, the 1934 Act Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and the putative Class. Those statements were materially false and misleading by their failure to disclose a true and accurate picture of BELLUS's ability to successfully design and conduct a Phase 2 trial. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing BELLUS securities to be artificially inflated. Plaintiff and other Class members purchased and/or acquired BELLUS securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

195. The 1934 Act Defendants were deliberately reckless in not knowing or turning a blind eye to the fact that BELLUS was struggling to enroll quality patients in its Phase 2 trial and had disregarded, in designing its Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated. Nonetheless, the 1934 Act Defendants made materially false and misleading public statements that provided false information to investors about the Company's capabilities and success. Thus, shares of BELLUS's common stock continued to trade at levels artificially inflated by the 1934 Act Defendants' misleading justifications for the negative information that was partially revealed on April 7, 2020, and the artificial inflation in BELLUS's share price persisted until it was fully removed on July 6, 2020.

April 6, 2020 Partial Disclosure

196. After the market closed on April 6, 2020, BELLUS announced the "completion of dosing in Phase 2 RELIEF trial with BLU-5937 for the treatment of refractory chronic cough,"

prompting an investor call with Defendants Bellini and Bonuccelli hosted by Jefferies LLC.⁶⁵ As later described in an analyst report issued on April 13, 2020, during the investor call, Defendants Bellini and Bonuccelli portrayed that “[the Company] remained confident of Ph2 success” but also disclosed that it was “currently working on the scenario planning for the next step (Ph2b vs. Ph3)” (4.13.20 Analyst Report). Company management acknowledged that “as the ongoing Ph[ase] 2 [trial] evaluates 10-fold dose range (25, 50, 100, 200mg), [BELLUS] expects the study would give some indication of dose selection.” However, the Company then revealed, “*[i]f no minimum efficacy dose is observed, a small Phase 2b may be necessary.*”

197. On this news, the Company’s stock price fell \$1.00, or 9% to close at \$10.00 on April 9, 2020, after two days of heavy trading. The 4.13.20 Analyst Report noted skepticism following the call with BELLUS management stating, in relevant part, that “[i]f Ph2 data show comparable safety and efficacy (vs. Shionogi’s S-600918) with good indication for dose selection, we view a meaningful upside potential from current valuation.”

198. The potential need for an additional Phase 2 study, prior to starting the next clinical phase, was reiterated in a “fireside chat” with Defendants Bellini and Bonuccelli, hosted by Guggenheim Securities, LLC, which was then detailed in an analyst report issued on April 16, 2020 (“4.16.20 Analyst Report”).⁶⁶ During this chat, Defendants Bellini and Bonuccelli “emphasized that *going directly into a phase 3 will come down to dose certainty after seeing the phase 2a results*, otherwise the company may plan to perform some dose confirmation work before phase 3.” Despite the continued narrative of a potential need for a Phase 2b trial, the 4.16.20 Analyst Report noted that, “[o]verall, we came away incrementally more positive into phase 2

⁶⁵ Jefferies LLC, *BELLUS: Investor Call with BLU Management* (April 13, 2020).

⁶⁶ Guggenheim Securities, LLC, *BLU (Buy) – Takeaways From Our Fireside Chat with Management* (Apr. 16, 2020).

data, with Bellus walking through its powering assumptions and BLU-5937 profile (PK, onset, and receptor occupancy)."

July 6, 2020 Class Period Ending Disclosure

199. Before markets opened on July 6, 2020, BELLUS announced the "topline results from its Phase 2 RELIEF trial of BLU-5937 in patients with refractory chronic cough," revealing that the trial "***did not achieve statistical significance*** for the primary endpoint of reduction in placebo-adjusted cough frequency at any dose tested."⁶⁷ Only "[a] clinically meaningful and highly statistically significant placebo-adjusted reduction in cough frequency was achieved in a pre-specified sub-group of high cough count patients (all patients at or above the baseline median average of 32.4 coughs per hour)," so the Company intended to move "forward into an adaptive Phase 2b trial enriched for higher cough count patients. We expect to begin this trial in the fourth quarter of 2020." On this news, the Company's stock price plummeted over **75%** from the Class Period high of \$12.02 on June 29, 2020 to close at \$2.97 on July 8, 2020 on extremely heavy trading volume.

200. As noted in a July 6, 2020 article titled, "Why Bellus Health Stock Tanked 69.2% Today" by Todd Campbell of The Motley Fool, shares of the Company "were falling 69.2% at 2:40 p.m. EST on Monday following its announcement that a ***phase 2 trial of BLU-5937 as a treatment for refractory chronic cough has missed its mark.***"⁶⁸ Mr. Campbell further noted that "[t]he long-shot hope could be that management is able to launch another study comprising

⁶⁷ BELLUS Health Announces Topline Results from its Phase 2 RELIEF Trial of BLU-5937 for the Treatment of Refractory Chronic Cough, BELLUS HEALTH INC. (July 6, 2020), <https://ir.bellushealth.com/node/9651/pdf>.

⁶⁸ Todd Campbell, Why Bellus Health Stock Tanked 69.2% Today, THE MOTLEY FOOL (July 6, 2020), <https://www.fool.com/investing/2020/07/06/why-bellus-health-is-tanking-63-today.aspx>.

patients with high cough counts that pans out, but there's no telling if or when such a trial would actually begin enrolling anyone."

201. Similarly, in a July 6, 2020 article titled "Bellus stock drops 72% after highly anticipated drug disappoints in human trials," Sean Silcoff of The Globe and Mail reported that the Company was "planning a follow-on study later this year on **250 patients** to further explore the drug's effectiveness among those that responded best in the first study."⁶⁹ The article also quoted BELLUS Board of Directors member Clarissa Desjardins as stating that "We are very much reassured we have a drug here But ***it's going to take longer and cost more money.***"

202. Likewise, in a July 6, 2020 analyst report titled "'5937 COUGH PH2 MISSES; HIGH-COUGH SUBPOP EFFICACY SUPPORTS PH2B START," Cowen and Company, LLC noted that: "***this data was disappointing given lack of statistics and dose response***" and saw "this result as a delay to Bellus' competitive timing in the RCC space, while the ***efficacy profile remains tbd.***"⁷⁰ The report added, "***the unusually low baseline cough counts compared to competitive trials underscore the need to improve design and rigor*** in ongoing rCC trials."

203. Further, as a result of this revelation, the market questioned BELLUS's ability to capitalize on patients who experience lower cough counts. As the July 6, 2020 analyst report titled "RELIEF Trial Misses Primary Endpoint; However Path Forward Becomes Clear; Reit Buy and \$28 PT" by Andrew S. Fein of H.C. Wainwright & Co., LLC reported, "the biggest contributing factor to the RELIEF trial missing its primary endpoint was the dilution of chronic cough patients who chronic cough is driven by hypersensitization", meaning "patients who experience lower

⁶⁹ Sean Silcoff, *Bellus stock drops 72% after highly anticipated drug disappoints in human trials*, THE GLOBE AND MAIL (July 6, 2020), <https://www.theglobeandmail.com/business/article-bellus-stock-drops-72-after-highly-anticipated-drug-disappoints-in/>.

⁷⁰ Cowen and Company LLC, '5937 Cough Ph2 Misses; High-Cough Subpop Efficacy Supports Ph2b Start, (July 6, 2020).

cough counts could have less P2X3 hypersensitization involvement.”⁷¹ Fein went on to add, “*[s]ince the profile of BLU-5937 is in line with competitors [for P2X3 receptor occupancy] we see a variable source of error coming from patients cough dependence on P2X3.* In turn, this could suggest a greater role of P2X3 hypersensitization for patients with higher cough counts over lower cough counts.”

204. And in a July 6, 2020 analyst report titled “No Relief from RELIEF – Primary Endpoint Missed. Still in the Race, But Substantially Higher Risk.”, David Martin of Bloom Burton Securities Inc. reported that “the missed primary endpoint, and the resulting uncertainty re: long term competitive positioning of the BLU-5937 are disappointing”, and “*class-leading positioning has become more difficult to envision.*”⁷² Martin added, “[a]t the same, we have *reduced the addressable market to 1.5 MM in the U.S. (previously 3.3 MM) due to the lack of efficacy in patients with <32 coughs/hour*”—shifting their rating to HOLD (was BUY).

205. Then, an July 7, 2020 analyst report titled “BLU – Downgrade to Neutral on Disappointing RELIEF Results” issued by Guggenheim Securities, LLC, reduced BELLUS’s addressable patient market in response to the announcement of RELIEF missing its primary endpoint, stating in relevant part, “[w]hile it is unclear how many patients in the moderate to severe cough category (~4M of 9M total patients with uncontrolled chronic cough) fall in Bellus’ potential cut-off for baseline cough count (~32 c/h), we update our model and remove any contribution from mild patients.”⁷³ The report went on to add that “[i]n a bear case scenario, P2X2/3 is an important

⁷¹ Andrew S. Fein, *RELIEF Trial Misses Primary Endpoint; However, Path Forward Becomes Clear; Reit Buy and \$28 PT*, H.C. WAINWRIGHT & Co, LLC (July 6, 2020).

⁷² David Martin, PhD, MBA, *No Relief from RELIEF – Primary Endpoint Missed. Still in the Race, But Substantially Higher Risk*, BLOOM BURTON & Co. (July 6, 2020).

⁷³ Guggenheim Securities, LLC, “BLU – Downgrade to Neutral on Disappointing RELIEF Results” (July 7, 2020)

driver of efficacy, and Bellus' compound as the most selective is at an efficacy disadvantage over the less selective compounds.”

VII. THE 1933 ACT CLAIMS

206. Plaintiff asserts strict liability claims under §§ 11, 12(a)(2) and 15 of the 1933 Act against BELLUS, the Individual Defendants and the Underwriter Defendants (the “1933 Act Defendants”), who signed and/or had authority over the contents of the Registration Statement and Prospectus (IPO Documents) issued in connection with the Company’s IPO. Plaintiff’s 1933 Act claims are not based on any allegation of deliberate or intentional misconduct, and Plaintiff expressly disclaims any reference or reliance upon fraud allegations for such claims and states these claims are entirely separate and distinct from the 1934 Act Claims asserted above. The 1933 Act Claims incorporate by reference Sections I, II, III, IV and V stated above, but only to the extent, that the allegations therein do not allege fraud, scienter, or the intent of the Defendants to defraud Plaintiff or the other members of the Class.

207. The 1933 Act Claims arise out of BELLUS’s approximately \$70 million IPO of 9,859,155 shares of common stock at \$7.10 per share.

208. On September 3, 2019, under the 1933 Act, BELLUS filed with the SEC, a Form-10 registration statement (the “Registration Statement”), listing on the first page, Defendants Jefferies, Cowen, Baird, Guggenheim Securities and Bloom Burton Securities underwriters for the IPO. In addition, the Registration Statement identified Defendants Jefferies, Guggenheim Securities and Bloom Burton Securities as “joint book-running managers”, with Defendant Cowen acting as lead manager and Defendant Baird acting as co-manager for the IPO. The Registration Statement was comprised of a preliminary prospectus supplement (the “Supplement”) to its short form base shelf prospectus (the “Base Prospectus”) dated July 26, 2019, that were also filed with the SEC, in accordance with the MDS.

209. Also on September 3, 2019, BELLUS issued a press release announcing the filing of the Registration Statement in connection with a proposed US\$60 million public offering of its common stock, and the filing of an application to list its common shares on the NASDAQ under the ticker “BLU”.⁷⁴

210. On September 4, 2019, BELLUS filed with the SEC a Form-10/A, amending its previously filed Registration Statement to include as Exhibit 3.1 the Underwriting Agreement. That same day, BELLUS received a letter from Will Slattery, Vice President of Listing Qualifications at NASDAQ certifying that the securities described in BELLUS’s Registration Statement had been approved for listing and registration upon official notice of issuance.

211. On September 5, 2019, BELLUS filed with the SEC its final amendment to the Registration Statement, constituting the prospectus (the “Prospectus”) for the IPO. The Prospectus revealed that the public offering price had increased to US\$70 million, or US\$7.10 per share for 9,859,155 BELLUS’s common stock.

212. That same day, BELLUS issued a press release announcing its common shares had begun trading on NASDAQ, the pricing of the IPO and that it had entered into an underwriting agreement with the Underwriter Defendants.⁷⁵ Specifically, the Underwriters had agreed to purchase all of the Company’s registered common stock for the upsized price of US\$70 million, paid as gross proceeds to BELLUS. In addition, the Underwriters were granted a 30-day over-allotment option following September 5, 2019, to purchase up to an additional 1,478,873 common shares from the Company.

⁷⁴ *BELLUS Health Announces the Launch of a US \$60 Million Public Offering of Common Shares in Canada and the United States and the Filing of an Application to List Its Common Shares on Nasdaq*, BELLUS HEALTH INC. (Sept. 3, 2019), <https://ir.bellushealth.com/node/6986/pdf>.

⁷⁵ BELLUS Health Inc., Prospectus Supplement (Form SUPPL) (Sept. 5, 2019), <https://www.sec.gov/Archives/edgar/data/1259942/000114420419043567/tv528906-suppl.htm>.

213. As stated above, the IPO was a firm-commitment offering, in which the Underwriter Defendants purchased shares of BELLUS and sold them to the investing public.

214. Under applicable SEC rules and regulations, the IPO Documents were required to disclose known trends, events or uncertainties that they were having, and were reasonably likely to have, and their impact on BELLUS's continuing operations. The statements contained in ¶¶ 216-17, 219, *infra*, were materially false and misleading because the IPO Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing its preparation, thereby rendering the 1933 Act Defendants liable pursuant to the federal securities laws.

215. After the truth became known, the Company's stock price plummeted. As a result, Plaintiff suffered substantial losses when he sold his shares of BELLUS stock for as low as \$2.89 on July 6, 2020, representing a 59.30% decline from the \$7.10 per share IPO price. On March 16, 2021, the day this action commenced, BELLUS's common stock closed at \$5.24 per share.

216. The IPO Documents contained multiple material misstatements regarding BELLUS's BLU-5937 and how it compared to Merck's gefapixant, stating in relevant part⁷⁶:

We believe that doses of 50 mg to 100 mg administered twice-daily (BID) would result in the desired level of therapeutic activity. ***In contrast, gefapixant, a product candidate in development by Merck & Co., was reported to cause taste alteration and/or taste loss in up to 80% of patients at the therapeutically relevant dose of 50 mg BID in a Phase 2 clinical trial.***

In July 2019, we enrolled our first patient in our ongoing Phase 2 clinical trial for BLU-5937 for the treatment of refractory chronic cough, with topline data expected in mid-2020.

⁷⁶ The particular portions of the statements alleged to be false or misleading are bold and italicized herein.

217. The IPO Documents specifically provided information about the clinical development of gefapixant as support for the expected efficacy BLU-5937:

The only clinically validated treatments in development for refractory chronic cough are molecules that inhibit the P2X3 receptor. Merck & Co.'s gefapixant, a low selectivity P2X3 inhibitor, is the most advanced in clinical development and is currently undergoing clinical evaluation in two Phase 3 trials. Gefapixant is a non-narcotic, low selectivity P2X3 inhibitor which has been shown to alleviate refractory chronic cough symptoms and improve patients' quality of life in Phase 2 clinical studies. Gefapixant's potent antitussive effect comes coupled with a significant tolerability issue in the form of taste alteration and partial or complete taste loss for a significant proportion of patients.

Results from an initial Phase 2, double-blind clinical trial in patients with refractory chronic cough showed that treatment with a high dose of gefapixant (600 mg BID) led to a significant reduction in mean daytime cough frequency compared with placebo. A subsequent dose-escalation trial confirmed the clinical activity of gefapixant in refractory chronic cough patients even when testing a much lower dose (50 mg BID). Across all Phase 2 trials, dose-dependent taste alteration and taste loss was the most commonly reported adverse event. In a Phase 2b trial in which 50 mg gefapixant was given twice daily, 81% of patients reported taste side effects, 48% of patients reported taste alteration, 24% had partial loss of taste and 21% had complete taste loss.

* * *

We are developing BLU-5937, a potent, highly selective, orally bioavailable small molecule inhibitor of the P2X3 receptor, as an oral therapy to reduce cough frequency in chronic cough patients. *Advances in the understanding of possible mechanisms underlying chronic cough have paved the way for product candidates targeting the P2X3 receptors, such as BLU-5937.*

218. The statements contained in ¶¶216-17 *supra* were materially false and misleading when made because the 1933 Act Defendants (i) mischaracterized the Company's ability to demonstrate efficacy in its Phase 2 trial of BLU-5937 by touting the efficacy demonstrated by the Merck's Phase 2 trial of gefapixant without disclosing that the design of the Company's Phase 2 trial was materially different from Merck's and was resulting in a low number of severe cough patients being enrolled and (ii) negligently promoted inhibiting the P2X3 receptor as a "clinically validated treatment" based on Merck's Phase 2 trials while disregarding, in designing the Company's Phase 2 trial, the correlation between high cough frequency and high efficacy that

Merck's trials had demonstrated.

219. In addition, while the 1933 Act Defendants list numerous "Risk Factors" in the IPO Documents, they failed to adequately warn investors that certain "Risk Factors" had already materialized at the time of the IPO. For example, the IPO Documents warned, in relevant part:

Competition in the biopharmaceutical industry is intense, and development by other companies *could render* BELLUS Health's drugs or technologies non-competitive.

* * *

There are multiple companies developing products at varying stages of development specifically intended to treat chronic cough including Merck & Co., Bayer AG, Shionogi Inc., Attenua Inc. and NeRRe Therapeutics Ltd, some of which have substantially greater product development capabilities and financial, scientific, marketing, and human resources than us. Of these companies, Merck, Bayer and Shionogi are developing P2X3 antagonists for chronic cough that *could compete* directly with BLU-5937.

220. The generic statements of "intense" competition and that other companies' drug development "could render" BELLUS's drug product(s) "non-competitive" and other P2X3 antagonists "could compete" with BLU-5937, contained in ¶219 *supra*, were materially false and misleading when made because the 1933 Act Defendants failed to disclose that the Company was falling behind its competitors not because of its competitor's development or pace of it, but because of its own poor design of its Phase 2 trial. BELLUS had disregarded the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated and set a low cough frequency threshold of 10 coughs per hour to enroll patients in the Company's Phase 2 trial, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS's Phase 2 trial meant it would inevitably not meet its designated primary endpoint for efficacy (even though Merck, Bayer and Shionogi all had successful Phase 2 trials), which would cause it to fail the Phase 2 trial, have to spend time and money on another Phase 2 trial, and to fall further behind Merck, Bayer and Shionogi in the race towards FDA approval and drug sales.

VIII. PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

221. During the Class Period, the artificial inflation of BELLUS's securities was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and misleading statements and/or omitted material facts about BELLUS's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of BELLUS and its business, operations, and prospects, thus causing the price of its securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and misleading statements and/or omissions during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

222. At all relevant times, the market for BELLUS's securities was an efficient market for the following reasons, among others:

- a. BELLUS's securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b. Over 78 million shares of BELLUS stock were outstanding, owned and/or publicly traded on the NASDAQ by hundreds, if not thousands, of persons;
- c. As a regulated issuer, BELLUS filed periodic public reports with the SEC and/or the NASDAQ;
- d. BELLUS regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging

public disclosures, such as communications with the financial press and other similar reporting services;

e. BELLUS was followed by at least 8 securities analysts employed by major brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. In addition, each of these reports were publicly available and entered the public marketplace;

f. Multiple market makers made a market in BELLUS's securities during the Class Period; and

223. During the Class Period, the price of BELLUS's securities responded quickly to incorporate and reflect new public information concerning the Company. As a result of the foregoing, the market for BELLUS's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in BELLUS's share price. Under these circumstances, all purchasers of BELLUS's securities during the Class Period suffered similar injury through their purchase of BELLUS's securities at artificially inflated prices and a presumption of reliance applies.

224. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the

importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

IX. NO SAFE HARBOR

225. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as “forward-looking statements” when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

226. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of BELLUS who knew that the statement was false and/or misleading when made.

X. CLASS ALLEGATIONS

227. Plaintiff brings this Action as a class action, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3), on behalf of a Class consisting of all persons and entities who purchased or otherwise acquired (a) common stock pursuant or traceable to the IPO Documents issued in connection with the Company’s IPO and/or (b) BELLUS securities during the Class Period and were damaged by the conduct asserted herein. Excluded from the Class are Defendants and their immediate families and legal representatives, heirs, successors or assigns and any entity in which the Defendants named herein have, or had, a controlling interest.

228. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. While the exact number of Class members is unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery, Plaintiff believes there are hundreds, if not thousands, of members in the proposed Class. Throughout the Class Period, millions of BELLUS securities were outstanding, owned and/or publicly traded on the NASDAQ by hundreds, if not thousands, of persons.

229. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the Class that predominate over those that may affect individual class members include whether:

- Defendants violated the federal securities laws;
- Defendants omitted and/or misrepresented material facts;
- Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- The 1934 Act Defendants knowingly or with deliberate recklessness, disregarded or turned a blind eye toward the fact that their Class Period statements were false and misleading;
- Individual Defendants caused BELLUS to issue false and misleading filings during the Class Period;
- The price of BELLUS securities was artificially inflated because of the Defendants' conduct complained of herein; and
- The Class members have sustained damages and, if so, the appropriate measure of damages.

230. Plaintiff's claims are typical of those of the Class members because they each were similarly damaged by Defendants' wrongful conduct in violation of the federal securities laws.

231. Plaintiff will fairly and adequately protect the interests of the Class members and has retained counsel who are experienced in securities class action litigation. Plaintiff has no interests that conflict with those of the Class.

232. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulties in the management of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT I
Violations of § 10(b) of the 1934 Act and
Rule 10b-5 Promulgated Thereunder
(*Against All Defendants*)

233. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. This claim is brought pursuant to § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10(b)-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, against all Defendants.

234. BELLUS, Defendant Smith, the Individual Defendant and the Underwriter Defendants carried out a plan, scheme, and course of conduct which was intended to, and did: (a) deceive the investing public, including Plaintiff and the other Class members, as alleged herein; and (b) cause Plaintiff and the other members of the Class to purchase BELLUS securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

235. During the Class Period, Defendants participated in the preparation of, approved and/or disseminated the false statements specified above, which they knew, or deliberately disregarded as, or turned a blind eye to, being misleading in that they contained misrepresentations and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

236. The Defendants named in this Count: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statement made, in light of the circumstances under which they were made, not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers or acquirers of BELLUS securities in an effort to maintain artificially high market prices for BELLUS securities in violation of § 10(b) of the 1934 Act and Rule 10b-5, promulgated thereunder.

237. Defendants, individually and together, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal the truth and/or adverse material information about the business, operation, and future prospects of BELLUS as specified herein.

238. Defendants employed devices, schemes and artifices to defraud, while possessing material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of BELLUS's value and performance and continued substantial growth, which included the preparation of and/or dissemination or approval of untrue statements of material facts and/or omitting to state material facts necessary in order to make statements made about BELLUS and its business operations and further prospects, in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and course of business which operated as a fraud and deceit upon the purchasers and acquirers of BELLUS securities during the Class Period.

239. Defendants had motive and opportunity to perpetrate the fraudulent scheme and course of conduct described herein. BELLUS, the Individual Defendants, and the Underwriter Defendants prepared and/or disseminated or approved the fraudulent IPO Documents. The

Underwriter Defendants delivered the IPO Documents to investors. Representatives of the Underwriter Defendants had ultimate authority and provided final approval for the contents of the IPO Documents before they were filed with the SEC and issued to the public.

240. The Individual Defendants were the most high-level executives and/or directors at BELLUS and members of the Company's management team or had control thereof. By virtue of their responsibilities and activities as a senior officer, the Individual Defendants were: (i) privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections, and/or reports; (ii) engaged in significant personal conduct and familiarity with the other defendants and were advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iii) aware of and/or participated in the issuing of statements and press releases on behalf of the Company, and each made false statements concerning the Company's abilities and had the opportunity to commit the fraud alleged.

241. The Defendants named in this Count had actual knowledge of the misrepresentations and/or omissions of material fact set forth herein or acted with reckless disregard for the truth in that they failed to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether the statements alleged herein, were false and/or misleading, or turned a blind eye toward the true facts that were available to them. The material misrepresentations and/or omissions of the Defendants in this Count were done knowingly or recklessly and for the purpose and effect of concealing the Company's true prospects from the investing public and supporting the artificially inflated price of BELLUS securities.

242. As demonstrated by BELLUS, Defendant Smith, the Individual Defendants and the Underwriter Defendants' misstatements and/or omissions of the Company's business, operations,

financial well-being, and prospects throughout the Class Period, these Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading, or turning a blind eye toward the true facts that were available to them.

243. As a result of the dissemination of the materially false and/or misleading information and failure to disclose material facts, as set forth herein, the market price of BELLUS securities was artificially inflated. In ignorance of the fact that market prices of BELLUS securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to, or recklessly disregarded, by Defendants, but not disclosed in public statements, Plaintiff and the other Class members acquired BELLUS securities at artificially high prices and were, or will be, damaged thereby.

244. At the time of said misrepresentation and omissions, Plaintiff and the other Class members were ignorant of their falsity and believed them to be true. Had Plaintiff and the other members of the Class, and the marketplace known the truth regarding the Company's business, which was not disclosed by Defendants, Plaintiff and the other member of the Class would not have purchased or acquired BELLUS securities, or if they had acquired such securities, they would not have done so at the artificially inflated prices that they paid.

245. By virtue of the foregoing, the Defendants named in this Count have violated § 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder.

246. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of BELLUS securities during the Class Period.

247. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

COUNT II
Violations of § 20(a) of the 1934 Act
(Against the Individual Defendants)

248. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. As members of BELLUS's executive team and/or the Company's board of directors, the Individual Defendants acted as controlling persons of BELLUS within the meaning of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

249. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of BELLUS's operations and/or intimate knowledge of the false information and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of BELLUS, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were provided with, or had unlimited access to BELLUS's reports, press releases, public filings and other statements, alleged by Plaintiff to have been misleading, prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

250. Each of the Individual Defendants had direct and supervisory involvement in the day-to-day operation of the Company and, therefore, are presumed to have had the power to control and/or influence the particular transactions giving rise to the securities violations, as alleged herein,

and exercised the same.

251. As set forth above, BELLUS and the Individual Defendants each violated § 10(b) and Rule 10b-5, promulgated thereunder, by their acts and omissions as alleged in this Complaint and the Class was damaged thereby. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to § 20(a) of the 1934 Act.

252. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of BELLUS securities during the Class Period.

253. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

COUNT III
Violations of § 11 of the 1933 Act
(Against BELLUS, the Individual Defendants and the Underwriter Defendants)

254. Plaintiff repeats and realleges every allegation contained in Sections I, II, III, IV, V, VII, VIII, IX, and X above as if fully alleged in this Count, only to the extent, however, that the allegation does not allege fraud, scienter, or the intent of the Defendants to defraud Plaintiff or the other members of the Class.

255. This claim is brought pursuant to § 11 of the 1933 Act, 15 U.S.C. § 77k, against BELLUS, the Individual Defendants and the Underwriter Defendants, on behalf of all persons and entities who purchased or acquired BELLUS common stock pursuant or traceable to the IPO Documents and were damaged by the conduct alleged herein. Plaintiff asserts only strict liability and negligence claims and expressly disclaims any claim of fraud or intentional misconduct. This Count does not sound in fraud. Plaintiff does not allege liability under this Count arises from any

scienter or fraudulent intent, which are not elements of a § 11 claim. All of the proceeding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count.

256. As part of the IPO Documents, BELLUS registered and sold approximately 9.86 million securities in the closing of the IPO. BELLUS was the issuer of its securities pursuant to the IPO Documents within the meaning of § 11 of the 1933 Act.

257. The Defendants named in this Count had ultimate control and/or authority over the contents and dissemination of the IPO Documents. Further, Defendants Bellini and Desjardins each signed the Registration Statement.

258. BELLUS common stock was issued and sold pursuant to the IPO Documents. All purchases or acquisitions of BELLUS common stock by shareholders pursuant or traceable to the IPO were a result of the issuance of the IPO Documents and the shares registered thereunder. Each share of common stock sold to investors by BELLUS and the Underwriter Defendants at the time of the closing of the IPO are traceable to the IPO Documents.

259. As alleged herein, the IPO Documents contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading. The facts misstated and omitted in the IPO Documents were material.

260. As the issuer and registrant, BELLUS is strictly liable for the untrue statements of material fact. The Defendants named in this Count owed to Plaintiff and the other Class members, the duty to make reasonable and diligent investigation of the statements contained in the IPO Documents, to ensure that the statements contained or incorporated by reference therein were true, and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. None of the Defendants named under this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements

contained in the IPO Documents were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

261. Plaintiff and the Class members did not know, nor in the exercise of reasonable diligence could they have known, that the IPO Documents contained untrue statements of material fact and omitted to state material facts required to be stated or necessary to make the statements identified herein not misleading when they purchased or acquired BELLUS common stock pursuant or traceable to the IPO Documents.

262. As a direct and proximate result of the conduct and omissions of the Defendants named in this Count, Plaintiff and the other Class members suffered substantial damages in connection with their purchase of BELLUS common stock pursuant or traceable to IPO Documents.

263. This claim is brought within one year of discovery of the untrue statements and omissions in the IPO Documents and within three years of their effective dates. By reason of the foregoing, the Defendants named in this Count are liable to Plaintiff and the Class under § 11 of the 1933 Act.

COUNT IV⁷⁷
Violations of § 12(a)(2) of the 1933 Act
(Against BELLUS and the Underwriter Defendants)

264. Plaintiff repeats and realleges every allegation contained in Sections I, II, III, IV, V, VII, VIII, IX, and X above as if fully alleged in this Count, only to the extent, however, that the allegation does not allege fraud, scienter, or the intent of the Defendants to defraud Plaintiff or the other members of the Class.

265. This claim is brought against BELLUS and the Underwriter Defendants pursuant to § 12(a)(2) of the 1933 Act, 15 U.S.C. § 77l(a)(2), on behalf of all persons who purchased or acquired BELLUS common stock pursuant to the IPO Documents and were damaged by the conduct alleged herein. Plaintiff asserts only strict liability and negligence claims and expressly disclaims any claim of fraud or intentional misconduct. This Count does not sound in fraud. Plaintiff does not allege liability under this Count arises from any scienter or fraudulent intent, which are not elements of a § 12(a)(2) claim. All of the proceeding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count.

266. The Defendants in this Count solicited, offered and/or sold BELLUS common stock using means or instruments of transportation or communication in interstate commerce or the mails.

⁷⁷ Plaintiff did not buy in the IPO directly from BELLUS, but asserts claims in this section on behalf of class members who did. Plaintiff has brought these claims because his own personal claims mean that he “possess[es] the same interest and suffered the same injury” as those class members who bought directly from BELLUS, therefore he has “the same necessary stake in litigating” the falsity of Defendants’ statements, which “gives the named plaintiff a sufficient stake in the outcome of her putative class members’ cases” to assert these claims. *See Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 94 (2d. Cir. 2018) (internal quotations and modification omitted); but see *Yi Xiang v. Inovalon Holdings, Inc.*, No. 16-CV-4923-VM, 327 F.R.D. 510, 519-21 (S.D.N.Y. 2018).

267. BELLUS and the Underwriter Defendants were sellers, offerors, or solicitors of purchasers of the shares offered pursuant to the IPO Documents.

268. As alleged herein, the IPO Documents contained untrue statements and/or omissions of material fact or facts necessary to make the statements, in light of the circumstances under which they were made, not misleading.

269. BELLUS common stock was issued and sold pursuant to the IPO Documents. All purchases or acquisitions of BELLUS common stock by shareholders in the IPO was a result of the issuance of the IPO Documents and the shares registered thereunder. Each security sold to investors by BELLUS and the Underwriter Defendants at the time of the closing of the IPO are traceable to the IPO Documents.

270. As issuer of the registered securities, BELLUS is strictly liable for the materially false and misleading statements and/or omissions of material facts, as described herein. BELLUS never made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the IPO Documents were accurate and complete in all material respects.

271. Nor did any of the Underwriter Defendants conduct a reasonable investigation or possess reasonable grounds for the belief that the statements contained in the IPO Documents were accurate and complete in all material respects. Had they exercised reasonable care, the Underwriter Defendants would have known of the material misstatements and/or omissions, as alleged herein.

272. Investors were solicited, offered and sold BELLUS common stock in the IPO pursuant to the IPO Documents that, as alleged herein, contained materially false and misleading statements and/or omissions of material facts therein and were damaged thereby. Moreover, these investors did not know, nor in the exercise of reasonable diligence could they have known, of the

untrue statements or omissions of material facts in the IPO Documents when they purchased or acquired their BELLUS common stock.

273. The Class members who purchased or otherwise acquired BELLUS common stock pursuant to the IPO from BELLUS or the Underwriter Defendants have sustained damages as a result of the materially false and misleading statements and/or omissions in the IPO Documents.

274. This Count is brought within one year of the discovery of, or reasonably could have discovered, the facts upon which this Count is based and within three years of the date that the securities upon which this Count is brought were sold to the public.

275. By reason of the foregoing, BELLUS and the Underwriter Defendants are liable for violation of § 12(a)(2) of the 1933 Act to Class members who purchased securities sold pursuant to the IPO Documents. These Class members also have the right to rescind and recover the consideration paid for these securities upon tender of their common stock to the Underwriter Defendants, and to recover rescissory damages to the extent they have already sold the securities.

COUNT V
Violations of § 15 of the 1933 Act
(Against the Individual Defendants)

276. Plaintiff repeats and realleges every allegation contained in Sections I, II, III, IV, V, VII, VIII, IX, and X above as if fully alleged in this Count, only to the extent, however, that the allegation does not allege fraud, scienter, or the intent of the Defendants to defraud Plaintiff or the other members of the Class.

277. This claim is brought pursuant to § 15 of the 1933 Act, 15 U.S.C. § 77o, against the Individual Defendants, on behalf of all persons and entities who purchased or acquired BELLUS common stock pursuant or traceable to the IPO Documents. For purposes of this claim, Plaintiff asserts only strict liability and negligence claims and expressly disclaims any claim of fraud or

intentional misconduct. This Count does not sound in fraud. All of the proceeding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count. For purposes of this Count, Plaintiff does not allege that liability under this Count arises from any scienter or fraudulent intent, which are not elements of a § 15 claim.

278. At all relevant times, the Individual Defendants were “controlling persons” of BELLUS within the meaning of § 15 of the 1933 Act.

279. BELLUS is strictly liable under §§ 11 and 12(a)(2) for the materially false and misleading statements and/or omissions in the IPO Documents.

280. The Individual Defendants violated § 11 by issuing the IPO Documents, which included materially untrue statements of fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading. Each Defendant named in this Count were controlling persons of BELLUS when the IPO Documents were filed and became effective due to their: (i) senior executive positions; (ii) positions on BELLUS’s board of directors; (iii) direct involvement in BELLUS’s day-to-day operations and in the review and/or approval of the IPO Documents; (iv) solicitation of BELLUS’s stockholders’ votes in favor of the issuance of BELLUS common stock; and/or (v) participation in and preparation of the IPO Documents.

281. By virtue of their exercise of control over BELLUS, the Individual Defendants had the power to, and did, influence and control, directly or indirectly, the decision-making of the Company, including the content of the IPO Documents and did not make a reasonable investigation or possess reasonable grounds for the belief that the IPO Documents were accurate and complete in all material respects. Had the Defendants in this Count exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

282. Plaintiff brings this claim within one year of discovering the untrue statements and omissions in the IPO Documents, and within three years of their effective dates. By reason of the foregoing, under § 15 of the 1933 Act, the Individual Defendants are liable to all persons and entities who purchased or acquired BELLUS common stock pursuant or traceable to the IPO Documents.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the Class, prays for relief and judgment, as follows:

- a) Declaring this Action to be a proper class action pursuant to Rule 23(a) and Rule 23(b)(3), certifying Plaintiff as Class Representatives pursuant to Rule 23(c), and appointing Roche Freedman LLP as Class Counsel pursuant to Rule 23(g);
- b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- c) Awarding Plaintiff and the Class pre-judgment and post-judgment interest, as well as, attorneys' fees, expert fees, and any other reasonable costs and expenses; and
- d) Awarding such other equitable, injunctive or further relief as the Court may deem just and proper.

XIII. JURY TRIAL DEMAND

Pursuant to Rule 38(b), Plaintiff respectfully demands a jury trial for all triable claims.

Dated: September 17, 2021

Respectfully submitted,

ROCHE FREEDMAN LLP

/s/ Ivy T. Ngo _____

Ivy T. Ngo (*pro hac vice*)

Velvel (Devin) Freedman

Constantine P. Economides

1 SE 3rd Ave., Suite 1250

Miami, Florida 33131

Telephone: (786) 924-2900

Emails: ingo@rochefreedman.com

vel@rochefreedman.com

ceconomides@rochefreedman.com

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM

Brian Schall (*pro hac* forthcoming)

1880 Century Park East, Suite 404

Los Angeles, CA 90067

Telephone: (424) 303-1964

Email: brian@schallfirm.com

Additional Counsel for Lead Plaintiff

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on September 17, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to counsel of record.

/s/ Ivy T. Ngo

Ivy T. Ngo